# 45

**STANDING COMMITTEE ON CHEMICALS & FERTILIZERS (2017-18)**

**SIXTEENTH LOK SABHA**

## MINISTRY OF CHEMICALS AND FERTILIZERS
**(DEPARTMENT OF PHARMACEUTICALS)**

**DEMANDS FOR GRANTS (2018-19)**

**FORTY FIFTH REPORT**

**LOK SABHA SECRETARIAT**
NEW DELHI

***March, 2018/ Phalguna, 1939 (Saka)***

**CC&F.No.45**

# FORTY FIFTH REPORT

## STANDING COMMITTEE ON CHEMICALS AND FERTILIZERS (2017-18)

## (SIXTEENTH LOK SABHA)

## MINISTRY OF CHEMICALS AND FERTILIZERS (DEPARTMENT OF PHARMACEUTICALS)

**DEMANDS FOR GRANTS (2018-19)**

*Presented to Lok Sabha on 13 March 2018*

*Laid in Rajya Sabha on 13 March 2018*

**LOK SABHA SECRETARIAT**
**NEW DELHI**
***March, 2018/ Phalguna, 1939 (Saka)***

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**COMPOSITION OF THE STANDING COMMITTEE ON CHEMICALS & FERTILIZERS (2017-18)**

**Shri Anandrao Adsul - Chairperson**

**MEMBERS**

**LOK SABHA**

2. Shri George Baker
3. Smt. Anju Bala
4. Shri B.N. Chandrappa
5. Shri Pankaj Chaudhary
6. Shri Sankar Prasad Datta
7. Dr. Ratna De Nag
8. Smt. Veena Devi
9. Shri R.Dhruvanarayana
10. Shri Innocent
11. Prof. A Seetaram Naik
12. Shri K. Ashok Kumar
13. Shri Chhedi Paswan
14. Smt. Kamla Devi Patle
15. Shri Rajendran S.
16. Dr. Kulamani Samal
17. Dr. Uma Saren
18. Dr. Krishna Pratap Singh
19. Shri Kirti Vardhan Singh
20. Smt. Rekha Arun Verma
21. Vacant

**RAJYA SABHA**

22. Shri Biswajit Daimary
23. Shri Prem Chand Gupta
24. Shri B.K. Hariprasad
25. Dr. Bhushan Lal Jangde
26. Shri Ranvijay Singh Judev
27. Shri Sanjay Dattatraya Kakade
28. Shri K. Parasaran
29. Dr. Sanjay Sinh
30. Shri Abdul Wahab
31. Vacant

**SECRETARIAT**

1. Shri V.K. Tripathi - Joint Secretary
2. Shri A.K. Srivastava - Director
3. Shri U.C. Bharadwaj - Deputy Secretary
4. Ms. Sonia Sankhla - Executive Assistant

## INTRODUCTION

I, the Chairperson, Standing Committee on Chemicals and Fertilizers (2017-18) having been authorised by the Committee to present the Report on their behalf, present this Forty Fifth Report on Demands for Grants of the Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals) for the year 2018-19.

The Committee examined the Demands for Grants (2018-19) pertaining to the Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals) which were laid in Lok Sabha and Rajya Sabha on 07 February, 2018.

The Committee took evidence of the representatives of the Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals) at their sitting held on 21 February, 2018.

The Report was considered and adopted by the Committee at their sitting held on 12 March, 2018.

The Committee wish to express their thanks to the Officers of the Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals) for their cooperation in furnishing the written replies and other material/information and for placing their views before the Committee.

For facility of reference and convenience, the Observations/ Recommendations of the Committee have been printed in bold letters at the end of the Report.

**New Delhi;**
***12 March, 2018***
***21 Phalguna, 1939 (Saka)***

**Anandrao Adsul**
**Chairperson**
**Standing Committee on**
**Chemicals and Fertilizers**

# REPORT

## CHAPTER – I

## INTRODUCTORY

### (A) Mandate of Department of Pharmaceuticals

The Cabinet Secretariat notified creation of a new Department, namely the Department of Pharmaceuticals, under the Ministry of Chemicals & Fertilizers which came into being w.e.f. 1st July 2008 with the objective to give greater focus and thrust on the development of pharmaceutical sector in the country and to regulate various complex issues related to pricing and availability of medicines at affordable prices, research & development, protection of intellectual property rights and international commitments related to pharmaceutical sector which required integration of work with other ministries.

Following works have been allocated to the Department of Pharmaceuticals:

1. Drugs and Pharmaceuticals, excluding those specifically allotted to other departments.
2. Medical Devices - Industry issues relating to promotion, production and manufacture; excluding those specifically allotted to other Departments.
3. Promotion and co-ordination of basic, applied and other research in areas related to the pharmaceutical sector.
4. Development of infrastructure, manpower and skills for the pharmaceutical sector and management of related information.
5. Education and training including high end research and grant of fellowships in India and abroad, exchange of information and technical guidance on all matters relating to pharmaceutical sector.
6. Promotion of public – private – partnership in pharmaceutical related areas.
7. International co-operation in pharmaceutical research, including work related to international conferences in related areas in India and abroad.
8. Inter-sectoral coordination including coordination between organizations and institutes under the Central and State Governments in areas related to the subjects entrusted to the Department.
9. Technical support for dealing with national hazards in pharmaceutical sector.
10. All matters relating to National Pharmaceutical Pricing Authority including related functions of price control/monitoring.
11. All matters relating to National Institutes for Pharmacy Education and Research.
12. Planning, development and control of, and assistance to, all industries dealt with by the Department.
13. Bengal Chemicals and Pharmaceuticals Limited.
14. Hindustan Antibiotics Limited.
15. Indian Drugs and Pharmaceuticals Limited.
16. Karnataka Antibiotics and Pharmaceuticals Limited.
17. Rajasthan Drugs and Pharmaceuticals Limited.

The work of the Department has been divided into three Divisions viz. Pharmaceuticals Industry Division, Public Sector Undertakings Division and R& D Division comprising of National Institute of Pharmaceutical Education & Research (NIPER). The National Pharmaceuticals Pricing Authority an attached office of this Department is entrusted with the work of fixation and revision of prices of pharmaceuticals products under Drug Price Control Order 2013.

**(B) Financial Performance of the Drugs and Pharmaceuticals Industry**

1.2 The Annual Turnover of the Indian Pharmaceutical Industry is estimated to be about Rs. 2197551 Croress during the year 2016-17. The share of export of Bulk Drugs, Drug Intermediates and Drug Formulations, Biologicals is Rs. 1076182 Croress for the year 2016-17.

This segment of Industry has shown tremendous progress in terms of infrastructure development, technology base and wide range of products. The industry has developed excellent GMP (Good Manufacturing Practices) compliant facilities for the production of different dosage forms. The strength of the industry is in developing cost effective technologies in the shortest possible time for drug intermediates and bulk activities without compromising on quality. This is realized through the country's strengths in Organic Chemical Synthesis and Process Engineering.

The domestic Pharma Industry has recently achieved some historic milestones through a leadership position and global presence as a world class cost effective generic drugs manufacturer for lifesaving drugs used for life threatening diseases for eg. AIDS, cancer etc. Along with Brazil & China, India has carved a niche for itself by being a top generic Pharma player. Many Indian companies are co partnering with foreign voluntary organizations for making available cheap generic drugs to lesser developed countries like Mozambique, Rwanda, South Africa and Tanzania which have about 33% of all people living with AIDS in Africa.

USA is also sourcing anti-Retroviral drugs from Indian Companies which are approved by USFDA, under many schemes. This is because the Indian Pharmaceutical companies maintain highest standards in purity, stability and safety, health and environmental Protection.

Top Indian Pharma companies have got various international regulatory approvals for their plants, from agencies like USFDA, MHRA-UK, TGA-Australia, MCC-South Africa etc. Outside USA, India has the highest number of USFDA approved plants for generic drugs manufacture. Major share of Indian Pharma exports is sourced to developed western countries especially USA. It speaks not only about the excellent quality of Indian pharmaceuticals but also about the reasonableness of the prices. Some of the leading Indian Pharma companies derive about 50% of their turnover from International business.

**(C) Exports**

1.3 Exports of medicinal and pharmaceuticals products for the last three years were as under:-

| Year | Exports of Medicines & Pharmaceuticals Products (Rupees in Crores) |
|---|---|
| 2013-14 | 90,356.00 |
| 2014-15 | 94,350.00 |
| 2015-16 | 1,10,522.77 |
| 2016-17 | 1,12,915.48 |

**(D) National Pharmaceuticals Pricing Policy**

1.4 The Department of Pharmaceuticals notified the National Pharmaceutical Pricing Policy-2012(NPPP-2012) on 07.12.2012 with the objective to put in place a regulatory framework for pricing of drugs to ensure availability of required medicines – "essential medicines" – at reasonable prices, even while providing sufficient opportunity for innovation and competition to support the growth of industry, thereby meeting the goals of employment and shared economic well being for all. The Government is now contemplating to introduce a new National Pharmaceutical Policy with the following objectives:

- Making essential drugs accessible at affordable prices to the common masses;
- Providing a longer term stable policy environment for the pharmaceutical sector;
- Making India sufficiently self-reliant in end to end indigenous drug manufacturing;
- Ensuring world class quality of drugs for domestic consumption & exports;
- Creating an environment for R&D to produce innovator drugs;
- Ensuring growth and development of the Indian Pharma Industry.

**(E) Foreign Direct Investment in Pharmaceuticals Sector**

1.5 The Government keeping in view the investment and technology required for growth of the domestic Pharma Sector has been amending the Foreign Direct Investment Policy from time to time. The instant FDI Policy for Pharma Sector allows Pharmaceuticals companies for Green Field Pharma Projects to invest 100% FDI through automatic route and for Brownfield Pharma Project Foreign investment upto 74% is permitted under automatic route and beyond that the companies have to come through Government approval route.

Union Cabinet in its meeting held on 24.05.2017 has approved abolition of the Foreign Investment Promotion Board. The administrative Ministries/ Departments are to process applications for FDI requiring Government approval. The proposals relating to Pharmaceuticals Sector are being handled by this Department, based on the Standard Operating Procedure (SoP) issued by Department of Industrial Policy & Promotion, and in consultation with related Government Agencies.

1.6 In response to a specific query of the Committee regarding how the new liberalized FDI policy in pharmaceuticals has boosted the sectors contribution in indian economy in terms of growth of green filed projects and brown field projects, job creation, increase in production and its impact on overall domestic pharmaceuticals sector, the Department in its written note stated as under:-

> "The major gain of this revised policy has been in the brown field projects and there too the significant gain has been in exposure to and transfer of new and innovative technologies. The business practices have improved to the global standards and today India has the largest number of USFDA approved manufacturers. It is also expected that such a liberal FDI policy will encourage and allow the Indian Pharmaceutical Industry to gain expertise in biologics and bio-similars which are the new frontiers of diseases treatment."

1.7 While replying to the query of the Committee about the grey areas which still need reform so that Indian pharmaceutical sector touch new commanding heights and policy initiatives that are being taken to address these grey areas, the Department in its written reply stated as under:-

> **"**The areas that need reform in the Indian Pharmaceutical Sector relate to 'ease of doing business', i.e., simpler and transparent procedures and guidelines for approval of drug manufacturing, licensing, quality control as well as stricter implementation of these guidelines. At present each State Government has the power to award the license to manufacture a drug. Therefore, one area of reform is standardization of the drug control regime. This, is the domain of Department of Health, and is being addressed by them. Another area of reform is to provide a level playing field to the indigenous manufacturers by correcting the inverted duty structure specially in case of medical devices. The duties on finished product is comparatively lesser in some cases than the duties on the raw materials required to produce a finished product. This needs to be corrected so that the indigenous manufactures are incentivized to import the raw materials/inputs and manufacture the finished products rather than importing the finish product itself. This has been taken up with the Department of Revenue."

1.8 **The detailed Demands for Grants (2018-19) of the Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals) were presented to the Lok Sabha on 7 February 2017. The demand shows a budgetary support of Rs.261.53 crores [(Rs. 261.47 crores (Revenue) + Rs.0.06 crores (Capital)]. The Committee have examined**

**in-depth the detailed Demands for Grants of the Department for the year 2018-19. The detailed analysis along with Observations/ Recommendations of the Committee are given in a separate chapter at the end of the Report. The Committee expect the Department to take all necessary steps for proper and timely utilization of funds ensuring completion of the various plans and projects in a time bound manner. The Committee also expect the Department to act on the recommendations of the Committee expeditiously.**

## CHAPTER-2

## REVIEW OF BUDGETARY PROVISIONS (2017-18)

Budget allocation along with actual expenditure incurred vis-à-vis BE and RE during the year 2017-18 were as follows:-

**(Rs. in croress)**

| Sr. No. | Name of the Scheme | Outlay | | | % Utilization with reference to RE (as on 09.02.2018) |
|---|---|---|---|---|---|
| | | BE 2017-18 | RE 2017-18 | Actual As on 09.2.2018 | |
| A. | Centre's Expenditure | | | | |
| 1. | Secretariat Economic Services | 13.30 | 13.30 | 10.42 | 78.35 |
| 2. | National Pharmaceuticals Pricing Authority (NPPA) | 15.00 | 14.42 | 8.09 | 55.47 |
| B. | Scheme Expenditure | | | | |
| 1. | National Institute of Pharmaceutical Education and Research(NIPER) | 127.73 | 151.66 | 123.19 | 81.22 |
| 2. | Assistance to PSUs (Loan to PSUs) | 0.06 | 0.06 | | |
| 3. | Schemes for Development of Pharmaceuticals Industry | 17.03 | 12.03 | 0.83 | 6.89 |
| 4. | Jan Aushadhi Scheme(PMBJP) | 74.62 | 74.62 | 47.64 | 63.84 |
| | Grand Total | 247.74 | 266.09 | 190.17 | 71.46 |

2.2 In view of the above, the Committee asked about the reasons for variations in RE and Actual utilization of funds during the year 2017-18 and also asked about the details whether the actual expenditure is likely to be substantially less than the enhanced fund at revised stage, the Department in their written note stated as under:-

> "The Department would be able to fully utilize the funds made available under RE 2017-18. Anticipated savings under Jan Aushadhi Scheme (PMBJP) and schemes for Development of Pharma Industry would be utilized for strengthening NIPERs. Accordingly, proposal for augmenting the allocation to NIPERs by Rs. 32.73crores has been sent as fourth supplementary to Ministry of Finance."

2.3 In continuation the Committee further asked about the break up of utilization of Rs. 32.73 crores among all NIPERs and give details of all four supplementary demand sent to Ministry of Finance in the year 2017-18 and their outcome in strengthening NIPERS. the Department in their written reply stated as under:-

"Details of proposed utilization of 4th Supplementary amounting to Rs. 32.73 crores are given below:

| NIPER | Rs. In crores |
|---|---|
| Grant –in-Aid General, Guwahati | 1.00 |
| Grants for CCA*, Guwahati | 12.15 |
| Grants-in-Aid Gen NIPER, Mohali | 0.58 |
| Grants for CCA, NIPER, Mohali | 14.00 |
| Grants for CCA, NIPER, Ahmedabad | 5.00 |

*CCA- Creation of Capital Assets

The Department did not avail first and third supplementary. Details of Second supplementary are given below:

(Rs. In Crores)

| Supplementary | Purpose | Amount | Status |
|---|---|---|---|
| First | - | - | - |
| Second | For providing support to NIPERs for construction, equipments and academic activities | 23.35 | 2nd supplementary has been approved by the Parliament. Accordingly RE 2017-18 has been revised and funds are being released. |

2.4 While furnishing the details of the constraints faced during utilization of funds under the plan schemes during the year 2017-18, the Department in their written note stated as under:-

> "The funds could not be utilized under scheme for Development of Pharma Industry as the proposals were not received. Under PMBJP against an allocation of Rs. 74.62 crores, an amount of Rs 47.62 crores has been released. DoP would consider releasing further installments after reviewing their physical and financial performance and receipt of expenditure statements."

2.5 In continuation the Department while furnishing the reasons for non submission of proposals made under the scheme Development of Pharma Industry and initiatives that are being taken by the Department to facilitate the proposals under this scheme and corrective measures to undo failures, stated as under:-

> "The scheme for Development of Pharma Industry has been appraised by SFC on 7.2.2018. The scheme has following five components:

(a) Cluster Development Program For Pharma Sector (CDPPS)
(b) Pharmaceuticals Promotion Development Scheme (PPDS)

(c) Assistance for Common Facilitation Center Bulk Drug Parks
(d) Assistance to Common Facilitation Center for Medical Device
(e) Pharmaceuticals Technology Up-gradation Assistance Scheme(PTUAS)

Components at (c ) (d) and (e) are new components. The detailed guidelines are being prepared for implementing the scheme. Cluster development scheme is being reviewed from time to time."

2.6 Further on being asked about the major physical and financial challenges that have posed obstacles to the growth of pharmaceuticals sector during the year 2017-18 and efforts made by the Department to address such challenges, the Department in their written note stated as under:-

"Pharmaceuticals Sector is a long gestation sector, because of the research and development work involved, whereas, the financial lending/term lending is of relatively shorter period. The industry therefore is demanding that the term of bank loan be extended to 7-10 years. Secondly, growth of pharmaceuticals sectoris also dependent on growth of new drugs through research and innovation. This also needs to be incentivized. For encouraging research activities the Government has provided income tax relief for R&D expenditure."

2.7 Committee further asked about the Department's evaluation of its budgetary performance during the year 2017-18 and its justification for underutilization of funds under various schemes/projects during the Annual plan year 2017-18, the Department in their written note stated as under:-

"The BE for 2017-18 is Rs. 247.74 crores and RE for 2017-18 is Rs. 266.09 crores. Expenditure as on 9.2.2018 was Rs. 190.17 crores. Department is making all efforts to utilize balance amount of budgetary allocation in 2017-18. As explained above the anticipated savings under schemes for Development of Pharma Industry and PMBJP are proposed to be utilized for strengthening of NIPER's."

2.8 The percentage to the total BE of the Department and actual utilization for the last two years and the current year in North-East Region is as under:

**(Rs. In croress)**

| | **Total B.E of the Department** | **Provision for North East Region** | | | **B.E. for North East Region as % of total B.E. of the Department** |
|---|---|---|---|---|---|
| **Year** | | **Budget Estimates( BE)** | **Revised Estimates( RE)** | **Actual** | |
| **2015-16 (Plan)** | 210.00 | 21.00 | 21.00 | 21.00 | 10.00 |
| **2016-17 (Plan)** | 160.00 | 19.52 | 26.28 | 26.27 | 12.20 |
| **2017-18 (Revenue)** | 247.74 | 31.52 | 38.87 | 31.50 | 12.72 |
| **2018-19 (Revenue)** | 236.03 | 33.52 | - | - | 14.20 |

2.9 Regarding physical targets that have been set under different schemes for North East Region, the Department in their written note stated as under:-

> "The entire provision for NER has been for NIPER Guwahati. Accordingly, physical target has been to complete the construction of NIPER-Guwahati campus on the land allocated by the State Government as well as academic activities. PMBJP Kendra's have been assisted in NER."

2.10 Responding to the achieved targets and outcomes towards development of North East Region in pharmaceuticals sector and its benefit to the people of North East during Twelfth plan period and 2017-18, the Department in their written note stated that so far, NIPER-Guwahati has awarded Master's Degree to 248 students and Ph.D Degree to 8 students. It is running from a rented building at present. Its own building is under advance stages of constructions.

## CHAPTER-3

## DEMAND FOR GRANTS (2018-19)

The proposed and approved BE of the Department of Pharmaceuticals for the year 2018-19 is as follows:-

**(Rs. in croress)**

| S. No. | | BE 2018-19 Proposed | BE 2018-19 Approved |
|---|---|---|---|
| **A.** | **Non Scheme** | | |
| | **Centre' Expenditure** | | |
| 1. | Secretariat General Service(DoP) | 20.45 | 14.00 |
| 2. | NPPA | 17.92* | 11.50 |
| **B.** | **Scheme** | | |
| 1. | Consumer Awareness, Publicity and Price Monitoring | | 4.00 |
| 2. | NIPERs | 300.00 | 135.00 |
| 3. | Assistance to PSUs | 0.06 | 0.06 |
| 4. | Development of Pharmaceuticals | 298.01 | 12.97 |
| 5. | Jan Aushadhi (PMBJP) | 120.00 | 84.00 |
| | **Total** | **756.44** | **261.53** |

*The scheme of Consumer Awareness, Publicity and Price Monitoring was covered under NPPA of BE 2018-19 proposal.

3.2 The Department of Pharmaceuticals proposed an outlay of Rs. 756.44 croress but only Rs. 261.53 croress were finally approved by the Ministry of Finance for financial year 2018-19. In this context, the Committee asked the Department to state whether the approved outlay of Rs.261.53 croress for 2018-19 will be sufficient for Department of Pharmaceutical to fulfill its mandate under various plan schemes and projects, along with the measures taken to mobilize additional fund requirement. The Committee also sought to know to what extent the development will suffer on account of low allocations. Responding to this the Department in its written reply stated as under:-

> "The approved outlay for 2018-19 would be insufficient to fulfill the mandate of the Department under various plan schemes and projects. NIPER division has sought Rs. 300 crores for the scheme for BE 2018-19 against which the allocation is Rs. 135.00 crores. However, the Department has advised the NIPERs to revise the user charges/fee etc and raise their own resources. A proposal for establishment of 10 NIPERs with estimated cost of Rs. 2048.96 crores for three years (including Rs. 1262.45 crores for 2018-19) has been sent to Ministry of Finance for approval by Expenditure Finance Committee. Funds will be sought from Ministry of Finance after approval of EFC. Scheme for Development of Pharmaceuticals has been appraised by SFC for Rs. 480.00 crores. The Department would seek additional

budget allocation from Ministry of Finance in 2018-19 through supplementary demand depending upon response to scheme and actual pace for expenditure."

3.3 Rs 12.97 crores have been finally approved for the year 2018-19 at BE stage against the proposed amount of Rs 298.01 crores under the scheme Development of Pharmaceuticals. In view of this the Committee asked about the reasons for this variation and why the Ministry of Finance could not be convinced to allocate funds under this scheme, the Department in their written note stated as under:-

" The scheme "Development of Pharmaceuticals Industry" has following five components:

(a) Cluster Development Program For Pharma Sector (CDPPS)
(b) Pharmaceuticals Promotion Development Scheme (PPDS)
(c) Assistance for Common Facilitation Center Bulk Drug Parks
(d) Assistance to Common Facilitation Center for Medical Device
(e) Pharmaceuticals Technology Upgradation Assistance Scheme(PTUAS)

Components at (c), (d) and (e) are new components while component (a) and (b) are continuing from 12th plan period. The SFC appraised the scheme on 7th February 2018. At the time of budget discussion the scheme was still under examination. Further the BE 2018-19 is consistent with Medium Term Expenditure Framework (MTEF). Guidelines for new components are being prepared and based on pace of expenditure Department may seek additional allocation."

3.4 Further the Committee sought scheme-wise information with regard to the physical and financial targets projected for the year 2018-19. The Department in their written note furnished the following details of physical and financial targets projected for 2018-19 which are as under:

**(Rs. In crores)**

| **Sl. No** | **Name of the Scheme** | **Physical Target Projected** | **Financial Target Projected** | **Budget Allocation 2018-19** |
|---|---|---|---|---|
| **1** | **NIPERs** | 500 Pharma experts<br>-Completion of building for NIPER-Guwahati subject to availability of funds.<br>**-**Starting of construction work of other NIPERs subject to availability of funds. | Rs. 300 crores in BE-2018-19 * | **135.00** |

| Sl. No | Name of the Scheme | Physical Target Projected | Financial Target Projected | Budget Allocation 2018-19 |
|---|---|---|---|---|
| **2** | **Development of Pharmaceuticals **** | | | |
| | Assistance to Bulk Drug Industry for Common Facility Centre | Commencement of construction of CFC's | 100.00 | 0.02 |
| | Assistance to Medical Device Industry for Common Facility Centre | Commencement of construction of CFC's | 75.00 | 0.02 |
| | Pharmaceuticals Technology Up-gradation Assistance Scheme(PTUAS) | | 72.00 | 0.02 |
| | Assistance for Cluster Development (CDP-PS) | Commencement of construction of CFC's. | 10.00 | 10.90 |
| | Pharmaceutical Promotion Development Scheme (PPDS). | Organization of India Pharma and India Medical Expo.<br>• Distribution of India Pharma Awards.<br>• Financial assistance to 20 or more Pharma and other Association for organizing seminars. | 2.00 | 2.00 |
| **3** | **PMBJP** | 1000 PMBJP Kendra's(2018-19). | 120.00 | 84.00 |

*****EFC proposal for establishment of 10 NIPERs has been sent to Ministry of Finance for seeking funds i.eRs. 2048.6 crores for three years (including Rs. 1262.45 crores for 2018-19)

******Physical and financial targets are as per SFC.

3.5 While replying to the query that whether the financial allocation under BE 2018-19 is adequate to achieve these targets, the Department replied that the financial allocation under BE 2018-19 is not adequate to achieve these targets. Additional funds would be sought from Ministry of Finance through supplementary demand during 2018-19 depending upon pace of expenditure.

3.6 In continuation to a specific query of the Committee that due to procedural delays and lack of scientific planning in utilization of funds the Department is not able to have funds in consonance to its proposals from Ministry of Finance and as a result of it the Department is seeking supplementary funds time and again**,** Department in their written note stated as under:-

> **"** No, the Departments projects the demands to the Ministry of Finance based on past experience and projected requirements. Ministry of Finance allocates the funds to the Department as per their policy and prioritization. The Department seeks supplementary grants as per requirement."

3.7 The capacity utilization of funds by the Department during the last five years are as under:

**(Rs. In crores)**

| Year | BE | RE | Actual |
|---|---|---|---|
| 2013-14 | 228.33 | 115.33 | 107.64 |
| 2014-15 | 247.87 | 137.04 | 123.87 |
| 2015-16 | 259.02 | 219.39 | 212.66 |
| 2016-17 | 211.40 | 211.40 | 307.56* |
| 2017-18 | 247.74 | 266.09 | **190.17** As on 9.2.2018 |

*Rs.100.00 crores was provided for loan to HAL in March 2017.

3.8 Further in light of the last five years data on capacity utilization of funds by the Department shows underutilization of total funds allocated to the Department, however the Department in their written note stated as under:-

> " As is evident from table above the pace of utilization of funds has improved significantly since 2015-16. During 2015-16, the Department utilized 96 percentage of RE and in 2016-17, the utilization was 98 percentage excluding the loan given to HAL. During the current year 71 percent RE allocation has been utilized till 9th February 2018. "

3.9 While replying to the query of the Committee about the onerous efforts that are being taken to prevent underutilization of allocated funds during the year 2018-19, the Department in their written note stated following efforts:-

> "(i) Expenditure is being reviewed on weekly basis and appropriate directions issued to all concerned.

(ii) All the NIPERs have been requested to prepare Annual activity and Annual Plan for timely utilization of funds in 2018-19. Progress will be monitored on regular basis through Steering Committee meetings, etc.

(ii) PMBJP is being implemented by BPPI. Regular meetings would be held with BPPI to monitor the progress of PMBJP."

**(A) <u>The Internal Extra Budgetary Resources (IEBR)</u>**

3.10 The Internal Extra Budgetary Resources (IEBR) in respect of Department of Pharmaceuticals is below:

**(a)<u>Autonomous bodies (IEBR)</u>**

**(Rs. Incroress)**

| **Name of Autonomous Bodies** | **Budget Estimates 2018-19** | | | | |
|---|---|---|---|---|---|
| **NIPERs** | **Internal Resources** | **Bond Debentures** | **E.C.B Suppliers Credit** | **Others** | **Total** |
| Mohali | 6.30 | NIL | NIL | NIL | **6.30** |
| Ahmadabad | 1.41 | | | | **1.41** |
| Guwahati | 0.75 | NIL | NIL | NIL | **0.75** |
| Hajipur | 0.43 | | | | **0.43** |
| Hyderabad | 4.37 | NIL | NIL | NIL | **4.37** |
| Kolkata | 1.02 | | | | **1.02** |
| Raebareli | 0.33 | NIL | NIL | NIL | **0.33** |

3.11 While furnishing the details of the IEBR generated by each NIPER for last five years, the department in their written note furnished the following data:-

**(Rs. In crores)**

| **Year** | **NIPER Mohali** | **NIPER Ahmedabad** | **NIPER Hajipur** | **NIPER Hyderabad** | **NIPER Guwahati** | **NIPER Kolkata** | **NIPER Raebareli** |
|---|---|---|---|---|---|---|---|
| **2012-13** | 7.34 | 0.8 | 0.36 | 1.27 | 0.45 | Not available | 0.28 |
| **2013-14** | 6.07 | 0.9 | 0.26 | 1.81 | 0.32 | Not available | 0.29 |
| **2014-15** | 5.6 | 1.4 | 0.31 | 1.99 | 0.45 | 0.42 | 0.25 |
| **2015-16** | 6.6 | 1.21 | 0.08 | 3.39 | 0.23 | 0.67 | 0.27 |
| **2016-17** | 5.4 | 1.35 | 0.37 | 3.74 | 0.65 | 0.87 | 0.28 |

3.12 Further responding to specific query of the Committee regarding sufficiency of the present rate of IEBR generation through internal resources to meet the fund requirement of NIPER institutions and the strategy to mobilize the requisite funds, the Department in their written note stated as under:-

> "The present rate of IEBR generation through internal resources are not sufficient to meet fund requirement of NIPER Institutions. All the NIPERs have been requested to generate revenues at least 1/3rd of their total expenditure every year by revising User Charges etc. Further steering committee has directed that faculty should earn their salary of four months, every year through Consultancies, Projects etc. Progress in this regard would be reviewed regularly by the Department as well as through Steering Committee."

**(b)Public Sector Undertakings (PSUs) (IEBR)**

**(Rs. In croress)**

| **Name of Public Sector Undertakings** | **Budget Estimates 2018-19** | | | | |
|---|---|---|---|---|---|
| | **Internal Resources** | **Bond Debentures** | **E.C.B Suppliers Credit** | **Others** | **Total** |
| BCPL | 8.00 | NIL | NIL | NIL | **8.00** |
| IDPL | NIL | NIL | NIL | NIL | **NIL** |
| HAL | NIL | NIL | NIL | NIL | **NIL** |
| KAPL | NIL | NIL | NIL | NIL | **NIL** |
| RDPL | NIL | NIL | NIL | NIL | **NIL** |

3.13 While furnishing the details of the IEBR generated by each PSU referred above for last five years, the department in their written note furnished the following data:-

**(Rs. In Crores)**

| **Year** | **BCPL** | **KAPL** | **IDPL** | **HAL** | **RDPL** |
|---|---|---|---|---|---|
| 2016-17 | 4.51 | 30.33 | A/c under preparation | | |
| 2015-16 | NIL | 19.51 | NIL | NIL | NIL |
| 2014-15 | NIL | 11.06 | NIL | NIL | NIL |
| 2013-14 | NIL | 9.76 | NIL | NIL | NIL |
| 2012-13 | NIL | 12.59 | NIL | NIL | NIL |

3.14 Further, while responding to the Committee with regard to reasons for dismal performance of the PSUs in generation of IEBR except BCPL, the Department in their written note stated as under:-

"All PSUs under the aegis of the Department, except KAPL are sick or incipient sick. IDPL, BCPL and HAL were declared sick and formally referred to BIFR since 1992, 1993 and 1997 respectively. The earlier revival/rehabilitation packages of IDPL, HAL & BCPL had also failed to achieve desired results. The production activities in RDPL have stopped after fire at its plant in October, 2016. HAL and RDPL are not in a position to even pay the salaries to their employees.

BCPL, after continuously reporting of losses for the last 65 years has turned around and earned operational profit of Rs. 4.51 cr. during 2016-17. BCPL has taken necessary steps to generate Internal Resources of funds. The turnaround of the Company became possible due to the better administration, dynamic leadership, Implementation of Centralized Payment/ Procurement/ Billing/ Collection/ Accounting systems etc. as well on account of reduction in the Operating and Administrative Costs."

3.15 Further replying to Committee query with regard to the feasibility of replicating similar initiatives in IDPL, HAL and RDPL, the Department in their written note stated as under:-

"These initiatives are part of the internal streamlining and reforms by the respective PSUs. As the Government has already decided to close IDPL and RDPL and strategically sell HAL, the feasibility of replicating the initiatives in these PUSs appears to be remote."

3.16 While furnishing the problems/constraints faced with respect to generation of the IEBR. The department in their written note stated as under:-

"All PSUs under the aegis of the Department, except KAPL are sick or incipient sick. IDPL, BCPL and HAL were declared sick and formally referred to BIFR since 1992, 1993 and 1997 respectively. The earlier revival/rehabilitation packages of IDPL, HAL & BCPL had also failed to achieve desired results. The production activities in RDPL have stopped after fire at its plant in October, 2016. HAL and RDPL are not in a position to even pay the salaries to their employees. They, for historical reasons, are unable to compete with the efficiency at which the private sector pharma companies are able to operate."

3.17 Further while responding to the extra efforts that are being taken to propel these PSUs to generate IEBR and increase the fund mobilization under IEBR, the Department replied as under:-

"The Cabinet has decided on 28.12.2016 to close IDPL & RDPL and strategically sell HAL & BCPL after meeting their liabilities from sale of their surplus land to government agencies. Subsequently, CCEA in its meeting held on 1.11.2017 has in principle decided for strategic disinvestment of 100% Government of India equity in KAPL."

## CHAPTER – IV

## REGULATORY MECHANISM

### (A) National Pharmaceuticals Pricing Authority (NPPA)

The National Pharmaceutical Pricing Authority (NPPA), an independent body of experts in the Ministry of Chemicals and Fertilizers was formed by the Govt. of India vide Resolution published in the Gazette of India No. 159 dated 29.08.97. The functions of NPPA, inter-alia include fixation and revision of prices of scheduled formulations under the Drugs (Prices Control) Order (DPCO), as well as monitoring and enforcement of prices. NPPA also provides inputs to Government on pharmaceutical policy and issues related to affordability, availability and accessibility of medicines.

4.2 The Government notified DPCO, 2013 on 15th May, 2013 in supersession of DPCO, 1995. Salient features of DPCO, 2013.

- The National List of Essential Medicines (NLEM), notified by the Ministry of Health & Family Welfare is adopted as the primary basis for determining essentiality and is incorporated in the First Schedule of DPCO, 2013 which constitutes the list of scheduled medicines for the purpose of price control.
- Ceiling prices of scheduled formulations are fixed based on 'market based data'.
- Price control is applied to specific formulations with reference to the medicine (active pharmaceutical ingredient), route of administration, dosage form / strength as specified in the First Schedule.
- The National List of Essential Medicines 2015 (NLEM 2015) was notified by the Ministry of Health and Family Welfare in December 2015. NLEM 2015 was thereafter notified as the First Schedule of DPCO 2013, in March 2016, by the Department of Pharmaceuticals.

4.3 The functions of the National Pharmaceutical Pricing Authority (NPPA) are:

- To implement and enforce the provisions of the DPCO, 1995 / 2013 in accordance with powers delegated to it.
- To undertake and/or sponsor relevant studies in respect of pricing of drugs/formulations.
- To monitor the availability of medicines, identify shortages, if any, and to take remedial steps.
- To collect/maintain data on production, exports and imports, market share of individual companies, profitability of companies etc. for bulk drugs and formulations.
- To deal with all legal matters arising out of the decisions of the Authority.
- To render advice to the Central Government on changes/revisions in Pharmaceutical policy.
- To render assistance to the Central Government in parliamentary matters relating to Pharmaceutical pricing.

4.4 A statement showing the Budget Estimates, Revised Estimates and Actual Expenditure for the NPPA during last three year (year-wise) and Budget Estimates for the year 2018-19 is as under:

**(Rs. In croress)**

| **Name of Scheme** | **2015-16** | | | **2016-17** | | | **2017-18** | | | **2018-19 (Revenue)** |
|---|---|---|---|---|---|---|---|---|---|---|
| **Revenue Head** | BE | RE | Actual | BE | RE | Actual | BE | RE | Actual as on 9.2.2018 | BE |
| **NPPA** | 5.00 | 3.0 | 1.49 | 11.21 | 10.29 | 9.25 | 15 | 14.42 | 8.09 | 11.50 |

4.5 Responding to the reasons for underutilization of funds provided to NPPA during 2015-16 and 2016-17 and no actual expenditure made by NPPA during 2017-18, the Department in their written note stated as under:-

> "There has been a slight underutilization of fund with respect to RE for the years 2015-16 and 2016-17. As regards 2017-18, expenditure could not be incurred due to issues related to opening of a separate Head for the Plan Scheme of Consumer Awareness, Publicity and Price Monitoring with certain sub-heads, and obtaining 15 digit numeric head for the Scheme. The matter regarding creation of appropriate head of account with 15 digit numeric codes in the Demand for Grants 2016-17 and 2017-18 was taken up with the Department of Pharmaceuticals. As per the directives received from DoP dated 31/01/2018, the budget head has been opened for the year 2018-19. Since the 15 digit head could not be created, therefore no expenditure could be incurred during the year 2017-18, under the scheme of Consumer Awareness, Publicity and Price Monitoring."

4.6 While replying to the initiatives that are being taken to ensure optimum utilization of funds by NPPA, the Department in their written note stated as under:-

> "A modified scheme "consumer Awareness, Publicity and Price Monitoring has been prepared. This modification was proposed to cater to the requirement of payment for setting up of Price Monitoring and Resource Units (PMRU). Under the revised scheme, PMRUs is proposed to be a registered society under the Chairmanship of the State Drugs Controllers. DO letters were sent by Chairman NPPA to Secretary (Health) of Kerala, Gujarat and Odisha for creation of societies enabling NPPA to release funds to these states after the approval of the modified scheme from DoP. The creation of the Society as proposed in the Scheme in the respective states would enable early release of funds by NPPA."

4.7 Further while replying to the query of the Committee whether NPPA has been successful in fulfilling their objective/mandate imparted to NPPA, if so, details thereof and if not, the reasons therefore, the department in their written reply stated that the objectives laid down in the scheme was achieved by undertaking the following activities during the year 2016-17:

a. National Conference on 'Affordable Medicines' held on 29th August, 2016 at Vigyan Bhawan, New Delhi. Seminar on this topic was also organized at NIPER, Mohali.

b. NPPA in collaboration with NIC developed a mobile-app (Pharma Sahi Daam) for dissemination of information on MRP of scheduled medicines by which the MRP of scheduled formulation can be searched on the basis of their generic names (pharmacological name) of specific strengths and dosages for which ceiling prices have been fixed or brand name. The app indicates the MRP of any scheduled medicine in any state based on ceiling price fixed by NPPA and VAT (now GST) in the state.

c. A tele-film on 'Affordability of Medicines' in Hindi for about 7 minutes duration was got prepared by NPPA through DAVP.

d. Price Monitoring and Resource Units (PMRUs) are being set up in the States of Kerala, Gujarat, Orissa, Assam and Maharashtra with the objective of monitoring the notified prices of medicines, detection of violation of the provisions of DPCO (revised from time to time), pricing compliance and ensuring availability of medicines. Financial assistance for setting up the PMRU for the year 2016-17 has been released to the States of Kerala, Odisha and Gujarat so far.

e. Rs. 32.21 lakhs was released to Doordarshan for telecast of tele-film on 32 Kendras for three times.

f. Rs. 23.64 lakhs was paid to LokSabha Television as per approved Media Plan for awareness /publicity campaign for 48 telecast of the tele-film.

g. Test samples were also purchased to identify the suspected cases of non-compliance of notified prices.

**(a) <u>E-Initiatives By NPPA</u>**

4.8 NPPA has also undertaken the following e-initiatives for better disposal of grievances of general public:-

**(i)** **Pharma Jan Samadhan (PJS):** PJS work as efficient grievance disposable mechanism system and as a database for public at large. The primary objective of PJS is to put in place a speedy and effective complaint redressal system with respect to availability of medicines, overpricing of medicines, sale of 'new drugs' without prior price approval (WPA) and refusal to supply or sell medicines. Complaints can be registered at **www.nppaindia.nic.in** and also at the toll free number **1800111255**.

**(ii)** **Integrated Pharmaceutical Database Management System (IPDMS) :** NPPA with the assistance of NIC developed a web- enabled information management system called Integrated Pharmaceutical Database Management System (IPDMS), which enables online submission of information by pharmaceutical manufacturers in the forms prescribed under the Drugs (Price

Control) Order 2013. Status of IPDMS registration and form filing as on 15.12.2017 is as follows.

| Companies Registered | Product Registered | Form II | Form V |
|---|---|---|---|
| 862 | 64908 | 9494 | 45734 |

**(iii) Mobile Application 'PharmaSahiDaam' and 'Search Medicine Price' utility:** Through this app anybody can easily search the brand name, composition, ceiling price and MRP of the formulation. This app can be downloaded from Google play store free of cost for Android based mobile phones and from Appstore for IOS based mobile Phone (iphone).
On NPPA Foundation Day on 29.08.2017, NPPA has entered into anMoU with National Anti-Doping Agency (NADA), Ministry of Youth Affairs & Sports to include information about medicines / substances prohibited in sports also for consumer awareness through NPPA's mobile app.

4.9 While furnishing regarding the response of common people to these e-initiatives and effort that are being taken to publicize these initiatives at village, block and district level of all states/UTs, the Department in their written note stated as under:-

"According to the information provided by NPPA, so far 425 cases have been processed under their e-initiative of Pharma Jan Samadhan. NPPA is disseminating from time to time the information on affordable medicines through advertisements in newspapers, radio, televisions and is creating awareness about government initiatives on affordable medicines amongst the general public."

4.10 Further, while responding to query whether the NPPA has taken any initiative to make public aware about fake drugs and unregistered drugs being sold in market, the Department in their written note stated that, the issues regarding quality and manufacture and marketing of drugs is the domain of Ministry of Health & Family Welfare through the Drug Controller General of India.

**(b) <u>Recovery of Overcharged Amount Under DPCO 2013 By NPPA</u>**

4.11 Since inception of NPPA, there are 1737 cases as on 31.12.2017 (1305 cases under DPCO 1995 & 432 cases under DPCO 2013) where demand notices have been issued by NPPA to Pharmaceutical companies. The status of these cases is as under:

**(Rs. In Croress)**

| Sl.No. | Particulars | DPCO 1995 | DPCO 2013 | Cumulative (Aug, 97 to 29.02.2016) |
|---|---|---|---|---|
| 1 | No. of cases (No.) | 1305 | 432 | 1737 |
| 2 | Overcharged amount demanded including interest whenever updated | 4988.64 | 974.49 | 5963.13 |
| 3 | Total amount realized | 546.10 | 273.66 | 819.76 |
| 4 | Amount outstanding (2-3) | 4442.54 | 700.83 | 5143.37 |
| 5 | Cases under Litigation including Cases referred to collector but contested by the companies in the court of law and in r/o Cipla Ltd. & its associate , where no coercive action can be initiated as per order of Supreme Court | 3460.80 | 173.88 | 3634.68 |
| 6 | Cases referred to collector & amount still to be recovered | 172.54 | 21.73 | 194.27 |
| 7 | Pending with BIFR/ Official Liquidator | 5.46 | 0 | 5.46 |
| 8 | Amount pending relating to the overcharging cases under process (4-(5+6+7) | 803.74 | 505.22 | 1308.96 |

Action for recovery of the overcharged amount along with interest thereon is a continuous process and NPPA takes action as per the provisions of DPCO'1995/ DPCO'2013 read with EC Act 1955. Recovery of the overcharged amount has been locked up in litigation, in a large number of cases in various High Courts and also in the Supreme Court.

4.12 While responding to the Committee query about the efforts that are being taken to make the recovery process easy and hassle free for the common people, the Department in their written note stated as under :-

> "An 'overcharged' amount is that amount which the defaulter (manufacturers/distributers/Chemists) has charged over and above the legal price from a common patient/customer illegally. For example if NPPA has fixed the ceiling of the price of the drug at Rs. X and if the defaulter is selling it at a price higher than X then the overcharged amount has to be recovered from the defaulter

concerned along with penalty. Therefore no recovery under the present statute and the drug price control order administered by Department of Pharmaceuticals, is made by or from the common people. An overcharged amount is recovered by NPPA from the overcharging manufacturers/distributers/chemists following a due process of law."

4.13 Further, responding to query whether all recovery cases can be taken to court or there is some lower limit above which only cases can be challenged in court, the Department in their written note furnished that all recovery cases can be taken to the court. Any aggrieved entity is free to approach the Judiciary on admissible grounds.

4.14 While furnishing the efforts that are being taken to provide free legal aid to people who are seeking such recovery from Pharmaceutical companies, the Department in their written reply stated that the occasion to provide legal aid to the persons affected by overcharging does not arise. The recovery is made by the NPPA/Government itself. Therefore, the question of legal aid to people does not arise.

**(c) Consumer Awareness Publicity And Price Monitoring**

4.15 Keeping in view the changing scenario in the pharmaceuticals sector and the recommendations of various committees, the ongoing Central Sector scheme has been re-named as "Scheme of Consumer Awareness & Publicity and Print Monitoring" from 2015-16 onwards. As per the SFC approval for the scheme, it has 2 components, a central component and a state component. The central component includes the joint publicity campaign by the NPPA and Department of Consumer Affairs on a 50:50 cost sharing basis. The state component of this scheme comprises setting up of Price Monitoring and Resource Units (PMRUs) at the State/Union Territories to provide all necessary support to the State Drug Controllers in carrying out monitoring and enforcement activities under the Drug Price Control Order, 2013 in their respective jurisdictions.

4.16 Provision for scheme "Consumer Awareness Publicity and Price Monitoring" in the year 2015-16, 2016-17 and 2017-18 was made under object head "Office Expenses": . The year wise allocation made and the expenditure incurred is shown in the following table.

**(Rs. In crores)**

| **Name of Scheme** | **2015-16 (Plan)** | | | **2016-17 (Plan)** | | | **2017-18 (Revenue)** | | | **2018-19 (Revenue)** |
|---|---|---|---|---|---|---|---|---|---|---|
| Revenue Head | BE | RE | Actual | BE | RE | Actual | BE | RE | Actual | BE |
| Consumer Awareness Publicity and Price Monitoring | 5.00 | 3.00 | 1.49 | 5.45 | 2.87 | 2.17 | 4.00 | 4.00 | 0 | 4.00 |

4.17 Responding to the specific query of the Committees on whether the Department has set any timeline by which these PMRUs will become functional in all States/UT and initiatives that are being taken by Department in coordination with States/UT to speed up the whole process, the Department in its written note stated as under:-

"The Modified scheme under approval envisaged creation of PMRUs in seven States on pilot basis. However, subsequently, this was limited to four States. No time limit has been fixed as such. Under the revised scheme, PMRU is proposed to be a registered society under the Chairmanship of the State Drugs Controllers with representatives from NPPA, Health Department of the State Government and of Civil Societies. DO letters were sent by Chairman NPPA to Secretary (Health) of Kerala, Gujarat and Odisha for creation of societies enabling NPPA to release funds to these states after the approval of the modified scheme from DoP. The creation of the Society as proposed in the scheme in the respective states would enable early release of fund by NPPA."

## CHAPTER-V

## SCHEMEWISE BUDGETARY PERFORMANCE

### (A) National Institute of Pharmaceutical Education and Research (NIPER)

Indian Pharma Industry has been a global leader in Generic drugs. In order to acquire leadership position in drug discovery and development and to continue to excel in the formulations, Government recognized that human resources/talent pool is very critical. National Institute of Pharmaceutical Education & Research (NIPER) at SAS Nagar (Mohali) was set up as a registered society in 1994 under the Societies Registration Act 1860, Subsequently the Institute was given statutory recognition by an act of Parliament, NIPER Act, 1998 and was declared as an Institute of National Importance.

During 2007-08, six new NIPERs were started at Ahmedabad, Guwahati, Hajipur, Hyderabad, Kolkata and Raebareli with the help of Mentor Institutes. Subsequently, NIPER at Madurai was approved in the year 2012. During 2015-16, Finance Minister in his Budget Speech announced 3 new NIPERs for the states of Chhattisgarh, Maharashtra and Rajasthan. The present status of NIPERs is as under:

| NIPER | Mentor Institute | Academic session started in | Status of land/construction |
|---|---|---|---|
| Mohali | - | 1998 | NIPER, Mohali has its own campus in 129.25 Acres of land. |
| Ahmedabad | - | 2007 | 60 acres land has been allocated and Hindustan Steelworks Corporation Limited (HSCL) has been selected as Project Management Consultant (PMC). Construction not commenced due to fund constraints. NIPER, Ahmedabad has been shifted to temporary constructed building on land allocated by Government of Gujarat in Gandhinagar. Foundation stone for construction of building was held on December, 2015. |
| Guwahati | Guwahati Medical College, Guwahati | 2008 | Foundation stone was laid on May, 2015. 89 acres land has been allocated and Engineering Projects India Limited (EPIL) has been selected as Project Management Consultant (PMC). Construction was started in June 2015, however due to fund constraints, construction has been delayed. As of date 37% construction |

| | | | |
|---|---|---|---|
| | | | is over. |
| Hajipur | ICMR - Rajendra Memorial Research Institute of Medical Science, Patna | 2007 | It has been decided to accept 12.5 acres of land offered by the Government of Bihar. |
| Hyderabad | CSIR-Indian Institute of Chemical Technology, Hyderabad | 2007 | 50 acres land has been allocated and National Project Construction Corporation Limited (NPCC) has been selected as Project Management Consultant (PMC). Construction not commenced due to fund constraints. |
| Kolkata | CSIR-Indian Institute of Chemical Biology, Kolkata | 2007 | Land has not been allocated so far. Matter has been taken up with the Government of West Bengal. Alternatively 25 acres surplus land of BCPL, a departmental PSU under strategic sale may be used. |
| Raebareli | CSIR-Central Drug Research Institute, Lucknow | 2008 | 45 acres land has been allocated. PMC is yet to be decided. Construction not commenced due to fund constraint. |
| Madurai | Being set up | - | 100 acres of land has been allotted by Government of Tamil Nadu in May, 2013. |
| (New Raipur), Chhattisgarh | Being set up | - | Government of Chhattisgarh has intimated that only 35 acre of land is available at the already selected site at New Raipur. They have also suggested 2 different sites of 63 acres and 116.94 acres for NIPER. Decision is yet to be taken. |
| (Nagpur), Maharashtra | Being set up | - | Land measuring 24.52 hectares (61 acres) has been allotted by Government of Maharashtra. |
| (Jhalawar), Rajasthan | Being set up | - | 100 acres of land has been allocated by State Government. Possession/lease agreement completed in March, 2017. Construction not commenced due to fund constraint. |

As per Annual Report of the Department all the existing NIPERs, except NIPER Mohali, are presently governed by a Steering Committee under the chairmanship of Secretary, Department of Pharmaceuticals. NIPER Mohali has its own Board of Governors. All NIPERs, except NIPER Hyderabad and NIPER, Hajipur have regular Directors. Process for their appointment is at final stages.

NIPER, Mohali has been ranked Number 2 and NIPER, Hyderabad as Number 5 in the country amongst the pharmacy colleges in the country as per National Institutional Ranking Framework (NIRF) Survey, 2017 by Ministry of Human Resources Development.

5.2 The aims and objectives of NIPER are:

(i) to nurture and promote quality and excellence in pharmaceutical education and research:
(ii) to concentrate on courses leading to master's degree, doctoral and post-doctoral courses and research in pharmaceutical education;
(iii) to hold examinations and grant degrees:
(iv) to confer honorary awards or other distinctions:
(v) to cooperate with educational or other institutions having objectives wholly or partly similar to those of the Institute by exchange of faculty members and scholars and generally in such manner as may be conductive to their common objective
(vi) to conduct courses for teachers, pharmaceutical technologies, community and hospital pharmacists and other professionals:
(vii) to collect and maintain world literature on pharmaceutical and related sciences and technology so as to develop an information centre of its own kind for other institutions within the country and in the developing world:
(viii) to create a central faculty of pharmaceutical instrumentation and analysis for use by the researches within and outside the Institute:
(ix) to have a centre to experiment and innovate and to train teachers and other workers in the art or science or pharmaceutical teaching:
(x) to develop a world level centre for creation of new knowledge and transmission of existing information in pharmaceutical areas with focus on national, educational professional and industrial commitments:
(xi) to develop a multi-disciplinary approach in carrying out research and training of pharmaceutical manpower so that the larger interests of the profession academia and pharmaceutical industry are better served and a pharmaceutical work culture is evolved which is in tune with the changing world trends and patterns of pharmaceutical education and research:
(xii) to organise national or international symposia, seminars and conferences in selected areas of pharmaceutical education, from time to time:
(xiii) to arrange courses catering to the special needs of the developing countries:
(xiv) to act as nucleus for interaction between academic and industry by encouraging exchange of scientist and other technical staff between the Institute and the industry and by undertaking sponsored and funded research as well as consultancy projects by the Institute: and
(xv) to pay due attention to studies on the distribution and usage of drugs by the rural masses, taking into account the socio-economic spectrum in the country.

5.3 The BE, RE and actual expenditure for the year 2015-16 to 2017-18 and BE for the year 2018-19 under the NIPER Scheme are as under:-

**(Rs. in croress)**

| Name of Institute | 2015-16 (Plan) | | | 2016-17 (Plan) | | | 2017-18 (Revenue) | | | 2018-19 (Revenue) |
|---|---|---|---|---|---|---|---|---|---|---|
| **Revenue Head** | **BE** | **RE** | **Actual** | **BE** | **RE** | **Actual** | **BE** | **RE** | **Actual** | **BE** |
| **NIPERs** | 98.96 | 84.21 | 82.42 | 80.50 | 73.73 | 73.73 | 96.23 | 112.81 | 88.21 | 101.50 |

5.4 While furnishing reply to whether the present allocation of Rs 101.50 croress is sufficient to achieve physical targets of NIPERs, if so, justify, if not, how much extra funds are required for the same, the Department in their written note stated as under:-

> "The Department has proposed an amount of Rs. 300 crores for NIPERs including NER component. As against that allocation is Rs. 135 crores including NER component. Present allocation though not sufficient to achieve physical targets regarding construction etc; may however suffice for the operation costs. NIPERs have been advised to revise user charges and fees etc., and to raise resources by working for industry. During the course of the year need based requisition for extra allocation will be considered."

5.5 Further it was also furnished by the Department that on direction of Ministry of Finance, Niti Aayog has carried out an evaluation of existing seven NIPERs , NITI Aayog has since submitted its report to Ministry of Finance. Report is enclosed at **Annexure-II**. Besides other recommendations, NITI Aayog has recommend to focus on strengthening the five NIPERs at Mohali, Ahmadabad, Guwahati, Hyderabad and Raebareli. It has also recommended that instead of opening new NIPERs, the limited budgetary resources be used for updating the existing institutes. In this respect a D.O letter from Hon'ble Minister (C&F) dated 12.01.2017 has been sent to Hon'ble Finance Minister stating that establishment of new NIPERs is the commitment of the Government, there is an urgent need to implement Government decisions without any further delay. Further approval of the combined EFC memo on 10 NIPERs and adequate funds for establishment of these NIPERs have been sought.

**(a) <u>National Centre For R&D in Bulk Drug</u>**

5.6 Department has proposed various specialized schemes for each NIPER in commencing stage. Accordingly, setting up of National Centre for R&D in Bulk Drug (NCRDBD) had been initiated, in order to promote inter-linkages with the industry, at the allocated site of NIPER-Hyderabad at Genome Valley of Medak District. SFC has approved Rs.54.20 croress in 2014. An amount of Rs.12 crores has been released in 2015-16.

5.7 The BE, RE and actual expenditure for the year 2015-16 to 2017-18 and BE for the year 2018-19 under the scheme are as under:-

**(Rs. In crores)**

| Name of Scheme | 2015-16 (Plan) | | | 2016-17 (Plan) | | | 2017-18 (Revenue) | | | 2018-19 (Revenue) |
|---|---|---|---|---|---|---|---|---|---|---|
| | BE | RE | Actual | BE | RE | Actual | BE | RE | Actual | BE |
| National Centre for R&D in Bulk Drug | 22 | 12 | 12 | 0.01 | 0 | 0 | 0.01 | 0.01 | 0 | 0 |

5.8 On being asked about the challenges that are coming in way of research and development of bulk drugs in the country and effective steps that are being taken to address these challenges, the Department in its written reply stated as under:-

> "The first and foremost challenge is availability of cheaper imported APIs after globalization, which has hit the indigenous bulk drug development (&industry) badly. The bulk drug industry is also highly polluting and its effluents are highly hazardous. The effluent treatment adds to the cost of production. The Government is envisaging a scheme for assistance of Bulk Drug Parks in which Govt. will fund the common facility including Effluent Treatment Plants. Secondly, Govt. has intervened to correct the inverted duty structure in bulk drugs."

5.9 While furnishing details about the inverted duty structure and how is it impacting the bulk drug production sector, the Department in their written note stated as under:-

> **"** Inverted duty structure is a situation where import duty on finished goods is low compared to the import duty on raw materials that are used in the productions of such finished goods. When the import duty on raw materials is high, the manufactured goods by domestic industry become uncompetitive against imported finished goods. At present, India is heavily depended on Bulk Drugs Imports. In order to incentivize domestic manufacturing, the government has intervened to correct inverted duty structure in bulk drugs."

**(b) <u>Scheme For Kala Azar And Anti TB Agents</u>**

5.10 Both the schemes came into being from the financial year 2012-13 with provision of Rs. 9.76 crores (Rs. 4.88 crores for each scheme). Rs. 2.44 crores has been released till date, for each scheme. Another Rs. 2.5 crores have been approved in Second Supplementary (2017-18)by the Parliament. The Department of Pharmaceuticals funded Anti TB and Kala Azar projects received its first grant on 31.3.2014 so the effective date of start of the project is considered as 01.4.2014. Details are given below:

(**Rs. In crores**)

| **Project Name** | **Sanctioned Amount** | **Grant received** | **Grant utilized** |
|---|---|---|---|
| Target Specific Drug Discovery Research against Anti Tuberculosis | **4.88** | **2.44** | **2.44** |
| Target Specific Drug Discovery Research against Kala Azar | **4.88** | **2.44** | **2.44** |
| **Total** | **9.76** | **4.88** | **4.88** |

5.11 On being asked about the constraints that are being faced during implementation of this scheme and effective steps that are being taken to address these constraints, the Department in their written note stated as under:-

> "The scientific discoveries/research or investigation cannot always be jacketed into a rigid time frame; especially discovery of new drugs for vexatious diseases like TB and Kala Azar. Promising leads are claimed to have been achieved and the evaluation of physical progress of the schemes have been done by Technical Expert Committee. The Committee has recommended for continuation of the scheme for further period of two year to complete the task beyond March, 2017 with no additional funds."

**(B) <u>Development of Pharmaceuticals Industry</u>**

5.12 The Department is preparing an Umbrella Scheme namely 'Scheme for Development of Pharma industry'. SFC in its meeting held on 7.02.2018 has recommended for approval of the scheme. The said Umbrella Scheme comprises of the following sub schemes:-

(a) Assistance to Bulk Drug Industry for Common Facilitation Centres

(b) Assistance to Medical Device Industry for Common Facilitation Centres

(c) Assistance to Pharmaceutical Industry (CDP-PS)

(d) Pharmaceuticals Technology Up-gradation Assistance Scheme (PTUAS)

(e) Pharmaceutical Promotion and Development Scheme (PPDS).

5.13 The Budget Estimates, Revised Estimates and Actual Expenditure for the last three year (year-wise) and Budget Estimates for the year 2018-19 under the Scheme for Development of Pharma industry is as under:-

**(Rs. In crores)**

| **Name of Scheme** | **2015-16 (Plan)** | | | **2016-17 (Plan)** | | | **2017-18 (Revenue)** | | | **2018-19 (Revenue)** |
|---|---|---|---|---|---|---|---|---|---|---|
| Revenue Head | BE | RE | Actual | BE | RE | Actual | BE | RE | Actual | BE |
| **Development of Pharmaceuticals Industry** | 27.00 | 12.25 | 8.75 | 19.48 | 8.25 | 7.62 | 17.03 | 12.03 | 0.77 | 12.97 |

The sub-schemes (i) Assistance to Bulk Drug Industry for Common Facility Centre and (ii) Assistance to Medical Device Industry for Common Facility Centre is a fresh initiative of the Department and was considered by the SFC in its meeting held on 7/2/2018 only.

5.15 During the power point presentation before the Committee, the Department furnished its Action Plan for 2018-19 under 'Scheme for Development of Pharma industry' with budget allocation of Rs 12.97 crores which is as under:-

(i) Initiation of Common Facility Centres in 2 Bulk Drug Parks under sub scheme Assistance to Bulk Drug Parks for Common Facility Centre which needs up to Rs.100 Crores;
(ii) Initiation of Common Facility Centres in 2 Medical Device Parks under sub-scheme Assistance to Medical Device Parks for Common Facility Centre which needs up to Rs.25 Crores;
(iii) Up-gradation to WHO-GMP standards of up to 100 units in private sector under sub-scheme Pharmaceuticals Technology Up-gradation Assistance Scheme(PTUAS);
(iv) Initiation of Common Facilities Centres in 3 Clusters promoted by Special Purpose Vehicle (SPV) under sub-scheme Cluster Development Programme for Pharma Sector (CDP-PS); and
(v) Conducting India Pharma and Indian Medical Expo; seminars, exhibitions etc. under Pharmaceutical Promotion & Development Scheme (PPDS).

**a) Cluster Development Programme for Pharma Sector (CDP-PS)**

5.16 With a vision to catalyze and encourage quality, productivity and innovation in pharmaceutical sector and to enable the Indian pharmaceutical industry especially SMEs to play a leading role in a competitive global market, Hon'ble Minister of Chemicals and Fertilizers approved the introduction of Cluster Development Programme for Pharma Sector (CDP-PS) on 27.10.2014. The CDP-PS is a Central Sector Scheme. The total size of the scheme is proposed as Rs.125 Croress for CDP-PS for 12th Five Year Plan.

The Scheme would be implemented on a Public Private Partnership (PPP) format through one time grant –in – aid to be released in various phases for creation of identified infrastructure and common facilities in the form of Common Facility Centers(CFC) to Special Purpose Vehicles (SPVs) set up for the purpose.

Assistance under the Scheme will be Rs. 20.00 Crores per cluster or 70% of the cost of the project, whichever is less for creation of common facilities. Some of the indicative activities under the Common facilities are:-

(i) Effluent Treatment Plants
(ii) Captive Power Plants
(iii) Steam and Cooling System
(iv) Incubation facilities
(v) Common Logistic Facilities
(vi) Advance common testing centre
(vii) Regulator awareness facility Center
(viii) Emergency Responses Center.

5.17 The Department furnished following reasons for shortfall in achievements under Cluster Development Programme for Pharma Sector which was approved in February 2014.

"Projects and Development India Limited (PDIL) has been chosen as the Project Management Consulting (PMC) for implementing the scheme. They have called for EOI/SPV for the 1st Phase, out of the six EOIs, one was found suitable by the Scheme Selection Committee (SSC) to be located in Tamilnadu. SSC has requested PDIL to call fresh EOI which they have done and the last date of receipt of the EOIs was 31/12/2015. After that PDIL has extended the date till 31.01.2016. The meetings of Scheme Steering Committee (SSC) have been held to review the response to EOIs and implementation of the Scheme."

)

5.18 Further Department furnished scheme wise break up of allocation made during last five years under Development of Pharmaceuticals Industry which is as under:

"The sub-scheme Pharmaceutical Promotion Development Scheme (PPDS) was considered by the SFC in its meeting held on 7/2/2018. For the pre existing scheme Cluster Development Programme for Pharma Sector (CDP-PS) which was announced in 2015, Rs. 12.5 crores for 2015-16, Rs. 9.99 crores for 2016-17 & 2017-18 each have been allocated.

**(Rs. In crores)**

| **Name of Scheme PPDS** | **BE** | **RE** | **Actual** |
|---|---|---|---|
| 2013-14 | 2.00 | 1.25 | 0.92 |
| 2014-15 | 2.00 | 1.50 | 1.45 |
| 2015-16 | 2.00 | 2.00 | 1.35 |
| 2016-17 | 2.00 | 1.25 | 1.13 |
| 2017-18 | 2.00 | 2.00 | **0.83 *** |

***as on 9.2.2018**

**(Rs. In crores)**

| Name of Scheme CDP-PS* | BE | RE | Actual |
|---|---|---|---|
| 2015-16 | 12.56 | 2.41 | 0.00 |
| 2016-17 | 10.00 | 2.00 | 1.49 |
| 2017-18 | 10.00 | 10.00 | |

*the scheme commenced from financial year 2015-16.")

5.19 Responding to the mark variation in BE, RE and actual utilization in the year 2016-17 and 2017-18 and reasons for this underutilization and steps that are under consideration to ensure optimum and timely utilization of funds allocation under this scheme, the Department in its written reply stated as under:-

> "In spite of the best efforts made by the government, the Cluster Development Programme for Pharma Sector (CDP-PS) scheme did not receive good response in 2016-17 and 2017-18. The Department is proposing to include the two existing schemes CDP-PS and PPDS as sub-schemes in the new scheme appraised by the EFC, 'Development of Pharmaceutical Industry'. This would help in proper utilization of the total budget allocated for the scheme as there would be flexibility in the utilization of funds.")

5.20 Responding to the Committee query on Cluster Development Programme for Pharma Sector(CDP-PS) which has not taken off despite best of the efforts and in what way the new umbrella scheme 'Development of Pharmaceutical Industry' will improve performance of CDP-PS, the Department in their written note stated as under:-

> "The Cluster Development Programme for Pharma Sector (CDP-PS) scheme could not take off despite the best efforts of the Government as the industry did not find the scheme attractive. Projects and Development India Limited (PDIL), the Project Management Consultant (PMC) had called for four expression of Interest (EOIs) and the responses were not encouraging in spite of the modification in the scheme and only one Special Purpose Vehicle (SPV) has been found suitable. The said scheme has been added as one of the five components of the scheme for "Development of Pharmaceuticals Industry" with a very meager budget allocation of Rs. 20.00 crores for 2018-2020, as part of umbrella scheme."

5.21 While furnishing replying to the query of the Committee about the extent to which the funds utilized under the Pharmaceuticals Promotion Development Scheme has been able to promote export in Pharmaceuticals sector in India and what more is required under this scheme to promote and develop pharmaceuticals sector, the Department in their written note stated as follows :-

- For exporting, the manufacturing units have to be GMP compliant.

- Assistances have been given to conduct the Conferences on 'Shifting Pharma Industry form Schedule-M to WHO-GMP Compliance' in various parts of the country.

- In the proposed new scheme there is a provision for Pharmaceuticals Technology Up-gradation and Assistance Scheme to incentivize GMP conversions.

**(C) Jan Aushadhi Scheme (PMBJP)**

5.22 Pradhan Mantri Bhartiya Janaushadhi Pariyojana(PMBJP) was launched by the Department of Pharmaceuticals, Ministry of Chemicals & Fertilizers, Government of India in November, 2008 across the country. The specific outlets are called 'Jan Aushadhi Stores'. Now, the 'Jan Aushadhi Scheme' has been revisited and renamed as 'Pradhan Mantri Bhartiya Janaushadhi Pariyojana' (PMBJP) and accordingly, 'Jan Aushadhi Stores' as 'Pradhan Mantri Bhartiya Janaushadhi Pariyojana (PMBJP) Kendras'. The scheme is being implemented through an agency namely Bureau of Pharma PSUs of India (BPPI) (the implementing agency of PMBJP) which is working under the administrative control of Department of Pharmaceuticals, Ministry of Chemicals &Fertilizers, Government of India.

The year wise details of budget allocation for PMBJP funds released to BPPI, utilization of funds by BPPI and number of PMBJP Kendra's opened from the inception of the scheme i.e since the year 2008-09, have been tabulated as under :-

**(Rs. In crores )**

| **Year** | **Budget Allocation** | | **Funds released to BPPI** | **Actual year wise utilization of funds** | **Number of PMBJP Kendra's opened** |
|---|---|---|---|---|---|
| | **BE** | **RE** | **AE** | | |
| 2008-09 | **NIL** | **NIL** | 1.72 | 0.55 | 7 |
| 2009-10 | **NIL** | **NIL** | 2.00 | 1.06 | 36 |
| 2010-11 | **NIL** | **NIL** | 3.00 | 1.20 | 54 |
| 2011-12 | **NIL** | **NIL** | **NIL** | 1.06 | 20 |
| 2012-13 | 20.00 | 4.50 | 1.66 | 2.25 | 37 |
| 2013-14 | 25.00 | 15.20 | 15.20 | 1.46 | 8 |
| 2014-15 | 30.00 | 9.67 | **NIL** | 13.76 | 14 |
| 2015-16 | 35.00 | 16.92 | 16.91 | 16.94 | 164 |
| 2016-17 | 35.00 | 49.75 | 49.75 | 51.97 | 740 |
| **Total** | **145.00** | **96.04** | **90.24** | **90.25** | **1080** |
| 2017-18 (As on 16.01.2018) | 74.62 | 74.62 | 47.64 | 29.63 | 1974 |
| **Total** | **219.62** | **170.66** | **137.88** | **119.88** | **3054** |
| 2018-19 | 83.99 | | | | |

5.23 The Department in their background note furnished following status of PMBJP Kendras:-

"The target of opening of 3,000 PMBJP Kendras across the country achieved on 08.12.2017 and as on 11.01.2018, 3,046 PMBJP Kendras are functional in 33 States/UTs of the country. A list of 3,046 functional PMBJP Kendras is as under:

| S. No. | State/UT | Total Number of functional PMBJP Kendras |
|---|---|---|
| 1 | Punjab | 68 |
| 2 | Delhi | 41 |
| 3 | Haryana | 67 |
| 4 | Uttar Pradesh | 475 |
| 5 | Uttrakhand | 93 |
| 6 | Madhya Pradesh | 86 |
| 7 | Tripura | 24 |
| 8 | Mizoram | 7 |
| 9 | Andhra Pradesh | 127 |
| 10 | Gujarat | 257 |
| 11 | Karnataka | 234 |
| 12 | Rajasthan | 92 |
| 13 | Maharashtra | 202 |
| 14 | Odisha | 66 |
| 15 | Chandigarh | 5 |
| 16 | Jammu & Kashmir | 32 |
| 17 | Himachal Pradesh | 26 |
| 18 | Jharkhand | 46 |
| 19 | Bihar | 85 |
| 20 | Kerala | 317 |
| 21 | Chattisgarh | 194 |
| 22 | Arunachal Pradesh | 24 |
| 23 | Telangana | 73 |
| 24 | Tamil Nadu | 245 |
| 25 | Assam | 49 |
| 26 | West Bengal | 40 |
| 27 | Nagaland | 11 |
| 28 | Manipur | 36 |
| 29 | Dadar& Nagar Haveli | 7 |
| 30 | Puducherry | 11 |
| 31 | Daman & Diu | 3 |
| 32 | Sikkim | 2 |
| 33 | Meghalaya | 1 |
| 34 | Andaman & Nicobar Islands | 0 |
| 35 | Goa | 0 |
| 36 | Lakshadweep | 0 |
| | **Total** | **3046** |

**As on 27.02.2018, 3195 PMBJP Kendra's are functional in 33 States/UTs of the country."**

5.24 Further the Department also furnished a list comparing the prices of generic medicines in PMBJP Kendras and branded medicines which is as under:

| S. No. | Medicine Name | Average Market Price of top three branded medicines (Rs.) | PMBJP's Price (Rs.) | % Savings |
|---|---|---|---|---|
| 1 | Amlodipine 5mg 10 Tablets | 20 | 3.24 | 83.80 |
| 2 | Atenolol 50 mg 14 Tablets | 22 | 5.56 | 74.72 |
| 3 | Clomiphene Citrate 50 mg 10 Tablets | 85.10 | 15.04 | 82.32 |
| 4 | Losartan 25 mg 10 Tablets | 26 | 5.74 | 77.92 |
| 5 | Metoprolol 50 mg 10 Tablets | 53 | 5.95 | 88.77 |
| 6 | Telmisartan 40 mg 10 Tablets | 70 | 12.64 | 81.94 |
| 7 | Atorvastatin 10 mg 10 Tablets | 70 | 8.02 | 88.54 |
| 8 | Cetrizine 10 mg 10 Tablets | 15.30 | 1.84 | 87.97 |
| 9 | Ramipiril 5 mg 10 Tablets | 72.80 | 9.68 | 86.70 |
| 10 | Fexofenadine 180 mg 10 Tablets | 125.69 | 27.54 | 78.08 |
| 11 | Ofloxacin 200 mg 10 Tablets | 52.60 | 14.80 | 71.86 |
| 12 | Oxaliplatin 50 mg Vial Injection | 3215.34 | 430.00 | 86.62 |
| 13 | Terbinafine 250 mg 7 Tablets | 94.33 | 31.66 | 66.08 |
| 14 | Citicoline 500 mg 10 Tablets | 457.66 | 169.88 | 62.88 |
| 15 | Levosulpiride 25 mg 10 Tablets | 67.91 | 9.49 | 86.02 |
| 16 | Tadalafil 20 mg 4 Tablets | 209.43 | 7.63 | 96.35 |
| 17 | Gemcitabine 1000 mg Vial Injection | 6412.04 | 631.21 | 90.15 |

5.25 The Department also furnished its Efforts to improve supply chain system of the Scheme which is as under:-

**"** Presently, 53 Distributors have been appointed in 27 States of the country, 8 Carrying & Forwarding (C&F) Agents have been appointed in 8 States of the country and 1 Central Ware House (CWH) has been established at Gurugram, Haryana to supply PMBJP products to PMBJP Kendras across the country. Recently, an end-to-end supply chain system has also been introduced through a SAP based software and an app at POS (Point of Sale) across the country for making available full range of medicines which is available at BPPI's CWH/CFA to all PMBJK's, through auto ordering and dispatches. Under this system, a professional agency has been appointed for providing end to end supply chain management solution for the scheme wherein medicines and other PMBJP products will be supplied from Central Ware House (CWH) to PMBJP Kendras directly to save time and cost."

5.26 Responding to the reasons for underutilization of funds as Rs. 74.62 croress has been allocated at RE stage but only Rs 29.63 croress has been the actual utilization under this scheme during the year 2017-18, the Department in their written note stated as under:-

"In Budget Estimates (BE) 2017-18, Rs. 74.62 Croress was allocated for PMBJP out of which Rs. 47.64 Croress has already been released to Bureau of Pharma PSUs of India (BPPI) (the implementing agency of PMBJP) in three (3) installments. DoP would consider releasing further installments after reviewing their physical and financial performance and receipt of expenditure statements."

5.27 Further, while responding to the Committee query regarding how many new PMBJP Kendra's are coming up in 2018-19 and physical targets that have been set for the year 2018-19 with increased BE allocation from Rs. 74.62 crores in 2017-18 to Rs. 83.99 croress in 2018-19 under this scheme, the Department in their written reply stated as under:-

"As per the three (3) year plan of the PMBJP i.e. 2017-18, 2018-19 and 2019-2020, 1000 more PMBJP Kendra's have been targeted to open in the country in each financial year beyond 2017-18 i.e. 2018-19 and 2019-2020."

5.28 While responding to the Committee concern over the fixing of responsibility for ensuring that the product basket in all the PMBJP Kendra are having 656 medicines and 128 surgical and consumables, the Department in their written note stated as under:-

"The Bureau of Pharma PSUs of India (BPPI) (the implementing agency of PMBJP) is responsible for ensuring the coverage of product basket of PMBJP and meeting the demands of the individual Kendra's. Presently, the product basket of the scheme covers more than 700 medicines and 154 surgical& consumables covering all major therapeutic groups such as Anti-infective, Anti-diabetics, Cardiovascular, Anti-cancers, Gastro-intestinal medicines, etc. As on 09.02.2018, 650 medicines and 85 surgical& consumables are available in Central Ware House (CWH) of BPPI for supplying to PMBJP Kendra's across the country. However, PMBJP Kendra are private enterprises. Products are supplied by BPPI to individual PMBJP Kendra's as per their demand."

5.29 Further while furnishing information about the monitoring mechanism that may ensure seamless supply of these products to the poor needy people and steps that are being taken to mark accountability in case of non-delivery of these services, the Department in their written note stated as under:-

"The Department is continuously monitoring the supply of medicines, surgical and consumables to PMBJP Kendra's under PMBJP. Following steps have been taken or are being taken to maintain continuous supply of medicines to PMBJP Kendra's across the country:

(a) Central Warehouse (CWH) of BPPI is located at IDPL Complex, Gurgaon where all the PMBJP products are stocked. All the Products procured from the manufacturers are kept at CWH and are available for supply after passing quality test conducted by NABL accredited laboratories.

(b) Carrying & Forwarding (C&F) Agents are the agents of BPPI responsible for stocking medicines, surgical, consumables and promotional items serving BPPI's Distributors, PMBJP Kendra's, Hospital Distributors and also, Institutional Supplies located in the States/UTs for which the respective C&F Agent is appointed.

(c) Distributors are independent medicine stockiest appointed to serve an assigned area. The Distributor is responsible for following:-

i)Procure drugs and medicines in a planned manner from BPPI for stocking and distribution.

ii)Procurement of orders from retailers, PMBJP Kendra's, Hospitals and Institutions in assigned area on a regular basis and execution of the same.

iii)Manage financial transaction of the PMBJP Kendra and act as feeder points of these to BPPI.

(d) As on date, BPPI has 8 Carrying & Forwarding (C&F) Agents and 53 Distributors across the country to ensure the timely supply of medicines to PMBJP Kendra's.

(e) Recently, BPPI has started end to end supply management solution from CWH to PMBJP Kendra's directly and accordingly, an agency has been appointed to supply the medicines and other PMBJP products directly to PMBJP Kendra's from CWH to reduce the time and cost.

(f) For an effective monitoring, BPPI has an independent branch to ensure the timely dispatch and availability of medicines on the PMBJP Kendra's. Moreover, the supply position is regularly reviewed at BPPI's Head office and also, at Department of Pharmaceuticals.

(g) Meetings are being taken by Hon'ble Minister (Chemicals & Fertilizers) / Hon'ble MOS (Chemicals & Fertilizers) / Secretary (Pharma) / Joint Secretary (Pharma) on weekly basis for reviewing the progress of the scheme. CEO, BPPI and other BPPI Officials attend the meetings for giving the latest status of PMBJP Kendra's, status of medicines &surgical at CWH, status of applications, status of MoUs with State Governments, status of MoUs with NGOs/Organizations/Trusts/Others, status of Marketing & Supply Chain and for discussion on the specific issues with Senior Officials of the Department."

## CHAPTER – VI

## REVIVAL/RESTRUCTURING OF PUBLIC SECTOR UNDERTAKINGS

### (A) Central Public Sector Enterprises (CPSEs)

There are five Central Public Sector Enterprises (CPSEs) under the administrative control of the Department of Pharmaceuticals. Of the five PSUs, three viz. Indian Drug & Pharmaceuticals Limited (IDPL), Hindustan Antibiotic Limited (HAL) & Bengal Chemicals & Pharmaceuticals Limited (BCPL) are sick and referred to Board for Industrial & Financial Reconstruction (BIFR). Rajasthan Drugs & Pharmaceuticals Limited (RDPL) has reported losses since 2013-14 and is incipient sick. Karnataka Antibiotic & Pharmaceuticals Limited (KAPL) is the only profit making CPSE.

**(As on 2015-16)**

| | **HAL** | **IDPL** | **RDPL** | **BCPL** | **KAPL** |
|---|---|---|---|---|---|
| **Established in** | 1954 | 1961 | 1978 | 1980 Nationalized | 1981 |
| **Classification** | Sick | Sick | Incipient Sick | Sick | Profit making |
| **Net worth ( in cr.)** | -488.10 | - 7147.23 | -24.65 | -184.60 | 127.81 |
| **Turnover ( in cr.)** | 15.12 | 84.22 | 36.53 | 88.19 | 326.90 |
| **Operating profit/loss( in cr.)** | -52.43 | 11.33 | -13.50 | 13.33 | 33.97 |
| **Liabilities ( in cr.)** | 1250 | 10779.20 | 121.05 | 230.55 | 9.06 |
| **Referred to BIFR** | 1997 | 1992 | No | 1992 | NA |
| **No. of Employees** | 1010 | 42 | 152 | 332 | 712 |
| **Officer level** | 250 | 7 | 52 | 70 | 239 |
| **Worker level** | 760 | 35 | 100 | 262 | 473 |
| **Total land** | 267 acre | 2003 acre | 9.35 acre | 72.89 acre | 37.34 acre |
| **Leasehold** | Nil | 1022 acre | 9.35 acre | 1.10 acre | Nil |
| **Freehold** | 267 acre | 981 acre | Nil | 71.79 acre | 37.34acre |

### (B) Cabinet decisions on Pharma PSUs

6.2 The Cabinet in its meeting held on 28.12.2016 decided that:

**i.** Only that much of surplus land of HAL, IDPL, RDPL and BCPL as would be required to meet the liabilities be sold through open competitive bidding to

Government agencies and the outstanding liabilities be cleared from the sale proceeds. Voluntary Separation Scheme/ Voluntary Retirement Scheme also be implemented in these PSUs to pave way for their closure. Remaining part of the land should be managed in accordance with guidelines of Department of Investment and Public Asset Management (DIPAM) and Department of Public Enterprises (DPE) in this regard and if need be, vested in a SPV created for this purpose.

**ii.** After liabilities have been met, balance sheet cleansed and the Voluntary Separation Scheme/Voluntary Retirement Scheme effected, the Department to close IDPL and RDPL and HAL and BCPL be put up for strategic sale.

**iii.** While taking a decision to close the PSUs, the Department may also explore the possibility of hiving off the subsidiary companies of HAL and IDPL for private participation, wherever found viable.

**iv.** 6.2.2 Cabinet Committee on Economic Affairs (CCEA) in its meeting held on 1.11.2017 has 'in principle' approved strategic disinvestment of 100% Government of India equity in Karnataka Antibiotics & Pharmaceuticals Limited (Karnataka Antibiotics & Pharmaceuticals Ltd.) Bengaluru through a two-stage auction process, wherein the first stage would lead to a shortlist of eligible bidders, and the second stage be competitive financial bidding. The valuation of the firm would be done using a combination of Discounted Cash Flow method, relative valuation and asset-based valuation of the firm's land.

**(C) <u>Scheme For Assistance to PSUs</u>**

6.3 Following is the BE, RE and Actual expenditure for the years 2015-16 to 2017-18 and BE for the year 2018-19 under assistance to PSU scheme:

**(Rs. In croress)**

| **Name of Scheme** | **2015-16 (Plan )** | | | **2016-17(Plan)** | | | **2017-18 (Revenue)** | | | **2018-19 (Revenue)** |
|---|---|---|---|---|---|---|---|---|---|---|
| **Revenue Head** | **BE** | **RE** | **Actual** | **BE** | **RE** | **Actual** | **BE** | **RE** | **Actual** | **BE** |
| **Loans to PSUs** | | | | | | | | | | |
| **HAL** | 0.01 | - | - | 0.01 | 0.01 | | 0.01 | 0.01 | | 0.01 |
| **BCPL** | 0.01 | - | - | 0.01 | 0.01 | | 0.01 | 0.01 | | 0.01 |
| **IDPL** | 0.01 | - | - | 0.01 | 0.01 | | 0.01 | 0.01 | | 0.01 |
| **RDPL** | 0.01 | - | - | 0.01 | 0.01 | | 0.01 | 0.01 | | 0.01 |
| **SSPL** | | | | 0.01 | 0.01 | | 0.01 | 0.01 | | 0.01 |
| **BIL** | | | | 0.01 | 0.01 | | 0.01 | 0.01 | | 0.01 |
| **Total** | **0.04** | | | **0.06** | **0.06** | | **0.06** | **0.06** | | **0.06** |

6.4 While furnishing reasons for keeping Rs.0.06 croress dormant since 2016-17 and whether this allocation is enough to assist the PSUs which are facing operational and management challenges in terms of shortfall in working capital, if not how much funds are actually required to address the issue of ailing PSUs. The Department in their written note stated that as stated earlier, only a token provision of Rs. 0.01 crores has been kept for each PSU since 2016-17. The same was not utilized as no major scheme/project was undertaken.

6.5 On being asked about the share of PSUs *vis-a-vis* private pharmaceutical companies in domestic and international drugs market and initiatives that are being taken to boost the performance of PSUs in both the markets, the Department in their written noted stated as under:-

> "The annual turnover of the Pharmaceutical Industry in the country is more than Rs. 2 lakh crores. Whereas the total turnover of the five Pharma PSUs is around Rs. 600 crores., i.e., only 0.3% of the total pharma production in the country. The pharma industry is a private enterprise driven industry and the contribution of the PSUs is quite negligible. As indicated earlier, the Government has already decided to either close or strategically sell the pharma PSUs."

6.6 Further the Committee noticed, since India is signatory of both WTO and TRIPS agreement due to which the advantage of process patent has been lost which gave boost to generic drugs production in the country. Now to meet the global and domestic demand of drugs under product patent regime what initiatives the PSUs are taking to innovate and discover indigenous drugs. the Department in their written note stated as under

> "The indigenous private industry is healthy, robust, competitive and fully capable to serve the societal and the Governmental needs. It is quite capable to cater to fulfill global and domestic requirements of drugs. In view of decision to close/ strategically sell the PSUs, no fresh initiatives are being taken by PSUs to innovate and discover indigenous drugs."

## Recommendations/Observations

### 1. Budgetary Performance during 2017-18

**The Committee note that during the year 2017-18 Rs 247.74 crores was allocated to Department of Pharmaceuticals at BE stage, which got increased to Rs 266.09 crores at RE stage but as on 9.02.2018 the actual expenditure of the Department of Pharmaceuticals has been only Rs 190.17crores which is Rs 75.92 crores short of the allocated budget. This reflects on poor budgetary planning and dissatisfactory fund utilization capacity of the Department of Pharmaceuticals, which would also result in lowering the pace of implementation of all crucial schemes viz. NIPERs, Jan Aushadhi (PMBJP) scheme for Development of Pharma Industry and assistance to PSUs. This also further contradicts the fund constraint argument given by the Department while explaining their inability to fulfill their physical targets under various schemes pending for want of sufficient funds.**

**The Committee also note that time and again the Department is resorting to supplementary grants from Ministry of Finance which has added an additional channel of approval with regard to funds allocation and disbursement apart from annual allocation. The Committee consider that this could have been avoided had the Department undertaken in-depth assessment of its budgetary requirements and thereafter had also utilized the allocated funds in a time bound manner. However, poor budgetary planning and delays in utilization of funds has not only affected Department's Budgetary performance but has also impacted its noble mandate of providing affordable drugs and medicals devices to the poor people of the country. The Committee**

**further note that relatively shorter financial lending terms for long gestation research and development projects of pharmaceuticals and need for incentivizing innovation activities are major obstacles to the growth of pharmaceuticals sector in the country.**

**The Committee therefore, strongly recommend the Department to stress upon scientific budgetary planning, effectively utilize allocated funds in time bound manner, enhance efficiency of its internal budgetary analysis, address structural and procedural lacunas coming in way of fund utilization and take up the issue of long term financial lending facility for long gestation pharmaceuticals projects and providing more tax incentives for such projects with the Ministry of Finance.**

**2. <u>Budgetary Performance of North East Region (NER)</u>**

**The Committee note that during the year 2017-18 at BE stage Rs. 31.52 crores was allocated for North East Region, which were increased to Rs. 38.87 crores at RE stage. As on 9.2.2018 the actual expenditure has been Rs. 31.50 crores. The BE for 2018-19 for NER has been estimated at Rs 33.52 crores and the entire provision is for NER has been for NIPER Guwahati and the physical target is to complete the construction of NIPER Guwahati campus on the land allocated by the State Government as well as academic activities. Besides PMBJP Kendra's have also been assisted in NER through this fund.**

**The Committee note that NIPER Guwahati started its academic session in 2008 with the help of mentor institute Guwahati Medical College. Foundation stone for construction of NIPER Guwahati's own**

**building was laid on May, 2015. 89 acres land has been allocated and Engineering Projects India Limited (EPIL) has been selected as Project Management Consultant (PMC). Construction started in June 2015, however due to fund constraints, construction has been delayed and as on date 37% construction has been done in past two and half years.**

**Since the entire allocation of NER is utilized for NIPER Guwahati that means from 2015-16 to 2017-18 a total of Rs. 78.77 crores has been spent on this and in only one-third of construction of NIPER Guwahati building has been completed. The Committee note that NER comprises of eight underdeveloped States Arunachal Pradesh, Assam, Manipur, Meghalaya, Mizoram, Nagaland, Sikkim and Tripura having 46 million population. To address the needs of NER, the Committee recommend to increase allocation for NER so that physical targets like NIPER Guwahati building project can be completed in a fixed timeframe. Further this increased allocation would also help PMBJP Kendra's in NER to receive adequate and timely fund assistance to attain business sustainability and extend the benefits of generic drug and medical devices to the common people of North East states. The Committee are of the view that the Department must explore the feasibility of equitable distribution of allocation meant for development of NER in Pharmaceuticals sector in all the 8 states instead of concentrating in one state for the inclusive development of this region.**

**3. <u>National Pharmaceuticals Pricing Authority (NPPA)</u>**

**The Committee note that during 2017-18 National Pharmaceuticals Pricing Authority (NPPA) were allocated Rs. 15 crores at BE stage which slightly got reduced to Rs 14.42 crores at RE stage**

**and actual expenditure as on 9.2.2018 has been assessed at Rs.8.09 crores. In 2018-19 Rs. 11.50 crores have been allocated for NPPA. The Committee also note that NPPA has convened National Conference on 'Affordable Medicines' in 2016, prepared a tele-film on 'Affordability of Medicines' through DAVP, taken e-initiatives like Pharma Jan Samadhan for grievance redressal, Integrated Pharmaceutical Database Management System (IPDMS) for online submission of information by pharmaceutical manufacturers , Mobile Application 'Pharma Sahi Daam' and 'Search Medicine Price' utility to facilitate easy search of the brand name, composition, ceiling price and MRP of the formulation.**

**The Committee note that NPPA has under-utilized its allocated funds in 2017-18 which might have impacted the outreach of its e-initiatives and other important functions. The Committee therefore recommend the Department to check underutilization of allocated funds with NPPA which though is an autonomous body and take sincere steps to optimally utilize the allocated funds. The Committee further recommend NPPA to monitor the availability and shortage of medicines in PMBJP Kendra's set up in all States/UTs.**

**The Committee also strongly urge upon NPPA to conduct regional conference in close coordination with Panchayati Raj and Urban Local Bodies and to arrange the tele-film on 'Affordability of Medicines' in every Panchayat Ghar of the country so that people at grass root level are given first hand information and knowledge about this. The Committee further would like the NPPA to include in their awareness campaign focus against use of spurious and expired medicines in under-developed States of the country.**

**4. <u>Consumer Awareness Publicity And Price Monitoring</u>**

**The Committee note that in the backdrop of the changing scenario in the pharma sector and the recommendations of various committees, the ongoing central sector scheme has been re-named as "Scheme of Consumer Awareness & Publicity and Print Monitoring" from 2015-16 onwards. As per approval of the Standing Finance Committee this scheme has 2 components, a central component and a state component. The central component includes the joint publicity campaign by the NPPA and Department of Consumer Affairs on a 50:50 cost sharing basis. The state component of the scheme comprises setting up of Price Monitoring and Resource Units (PMRUs) An amount of Rs. 5.45 crores was provided in BE (2016-17) which has been reduced to Rs. 2.87 crores under RE (2016-17) for the Scheme and actual expenditure was Rs 2.17 crores. Further the Committee note that during the year 2017-18 Rs. 4 crores were allocated at BE stage for modified scheme-Consumer Awareness, Publicity and Price Monitoring, which remained unaltered at RE stage however, expenditure could not be incurred due to issues related to opening of a separate Head for the Plan Scheme of Consumer Awareness, Publicity and Price Monitoring with certain sub-heads, and obtaining 15 digit numeric head for the Scheme.**

**Now in 2018-19 again Rs.4 crores has been allocated. The Committee note that the objectives of setting up the PMRUs are to provide necessary technical assistance to the State Drug Controllers and NPPA towards monitoring the notified prices of medicines, detection of violation of the provisions of DPCO, pricing compliance and ensuring**

**availability of medicines, monitoring the price movement of scheduled and non-scheduled formulations, collection and compilation of market based data of scheduled and non-scheduled formulations, collection of test samples of medicines from the retail market whenever required and conduct of training, seminars and workshops at the State and District levels for consumer awareness and publicity.**

**The Committee further note that this scheme was modified to cater to the requirement of payment for setting up of Price Monitoring and Resource Units (PMRU). The Modified scheme under approval envisaged creation of PMRUs in seven States viz Maharashtra, Gujarat, Orissa, Haryana, Kerala, Assam and Manipur on pilot basis. However, subsequently, this was limited to four States *viz*. Kerela , Gujarat, Odisha and Maharashtra and as such no time limit has been fixed. Under the revised scheme, PMRU is proposed to be a registered society under the Chairmanship of the State Drugs Controllers with representatives from NPPA, Health Department of the State Government and of Civil Societies. DO letters were sent by Chairman NPPA to Secretary (Health) of Kerala, Gujarat and Odisha for creation of societies enabling NPPA to release funds to these states after the approval of the modified scheme from Department of Pharmaceuticals. The creation of the Society as proposed in the Scheme in the respective states would enable early release of funds by NPPA.**

**The Committee would like the Department to convince each State and UT to have PMRU so that they can extend all necessary support to the State Drug Controllers in carrying out monitoring and enforcement activities under the Drug Price Control Order, 2013 in their respective**

**jurisdictions, which as on date is not up to the mark. As a result of this Indian drug market is adulterated with spurious and expired drugs. PMRUs once established will also ensure that the benefits of the DPCO trickle down to the grassroots level, which is the need of the hour. Thus, the Committee recommend the Department to work in close coordination with NPPA, State Drugs Controllers, State Health Department and likeminded Civil society representatives where PMRUs are being implemented on pilot basis. Thereafter based on the success of these pilot projects the scheme should be implemented in other states/UT within a fixed timeframe.**

**5. <u>National Institute of Pharmaceutical Education and Research (NIPER)</u>**

**The Committee note that in order to acquire leadership position in drug discovery and development and to continue to excel in the formulations, Government recognized that human resources/talent pool is very critical. National Institute of Pharmaceutical Education & Research (NIPER) at SAS Nagar (Mohali) was set up as a registered society in 1991 under the Societies Registration Act 1860, Subsequently the Institute was given statutory recognition by an act of Parliament, NIPER Act, 1998 and was declared as an Institute of National Importance. Further during 2007-08, six new NIPERs were started at Ahmedabad, Guwahati, Hajipur, Hyderabad, Kolkata and Raebareli with the help of Mentor Institutes. Subsequently, NIPER at Madurai was approved in the year 2012. During 2015-16, Finance Minister in his Budget Speech announced 3 new NIPERs for the states of Chhattisgarh,**

**Maharashtra and Rajasthan at New Raipur, Nagpur and Jhalawar respectively.**

**The Committee note that during the year 2017-18 Rs 96.23 crores were allocated to NIPER at BE stage which increased to Rs 112.81 crores at RE stage. However only Rs 88.21 was the actual expenditure. Rs 101.50 crores has been allocated for the year 2018-19 against the proposed demand of Rs 300 crores of the Department. Further, Expenditure Finance Committee proposal for 10 NIPERs has been sent to Ministry of Finance for seeking Rs. 2048.6 crores for next three years (including Rs. 1262.45 crores for 2018-19). The Committee note that on one hand department is proposing higher amount under this scheme and on the other hand unable to utilize the allocated amount despite of pending construction work and need of new technical instruments in these institutes.**

**The Committee further note that all the existing NIPERs except NIPER Mohali, are presently governed by a Steering Committee under the chairmanship of Secretary, Department of Pharmaceuticals. NIPER Mohali has its own Board of Governors. All NIPERs, except NIPER Hyderabad and NIPER, Hajipur have regular Directors and process for their appointment is at final stages. Since all NIPERs except NIPER Mohali are functioning in absence of Board of Governors so the Committee recommend that all NIPERs shall be governed by their own Board of Governors. They also recommend to expedite appointment of regular Directors for NIPER Hyderabad and Hajipur for effective governance and management of these institutes.**

**The Committee note that department has not been able to elevate NIPERs as institutes of excellence. All NIPER institutes except Mohali are reeling under multiple problems- fund crunch, insufficient internal resource generation, pending building construction, under paid adhoc and contractual faculty, and running courses in rented buildings without requisite infrastructure support. All this has lowered the prestige and defeated the purpose for which these institutes were set up. Thus, the Committee strongly recommend that all NIPERs shall be accorded with statutory status by an act of Parliament at par with NIPER Mohali. The Committee also recommend the Department to take prompt steps to give required financial handholding to NIPERs so that pending campus construction of all NIPERS is completed in a time bound manner and good salary packages can be offered to attract best faculty in these institutes. The Committee also endorse the NITI Aayog recommendation that there is need to re-engineer business model of the NIPERs in order to make them the "IITs of the Pharmaceuticals sector" and thus department shall choke out a suitable roadmap for smooth functioning of all existing NIPERs as they have to play a pivotal role in developing highly skilled human resource for expanding Indian Pharmaceuticals sector.**

**6. National Centre For R&D in Bulk Drug**

**The Committee note that the Department initiated setting up of National Centre for R&D in Bulk Drug (NCRDBD), in order to promote inter-linkages with the industry at the allocated site of NIPER-Hyderabad at Genome Valley of Medak District. Standing Finance Committee (SFC) has approved Rs.54.20 crores in 2014 for this**

**purpose. However, Rs. 12 crores was actual utilization under this scheme in 2015-16. During the year 2016-17 and 2017-18 only Rs 0.01 crores has been allocated but there is nil actual utilization in both the years. In the year 2018-19 as well no allocation has been done under this scheme. The Committee note that the first and foremost challenge is availability of cheaper imported Active Pharmaceutical Ingredients (APIs) after globalization, which has badly hit the indigenous bulk drug development & industry. The Committee further note that the bulk drug industry is highly polluting and its effluents are highly hazardous, whose treatment adds to the cost of production. For this the government has started a scheme for assistance to Bulk Drug Parks in which Govt. will fund the common facility including Effluent Treatment Plants. The Standing Finance Committee (SFC) has Further approved Assistance to Bulk Drug Industry for Common Facilitation Centre on 7.2.2018. The Committee recommend the Department to swiftly utilize the allocated funds under this scheme for Bulk Drug industry. The Committee also note that inverted duty structure is also adversely impacting the bulk drug production sector and recommend the Department to address the major issue of inverted duty structure so that import of bulk drugs can be checked and domestic bulk drug industry is made competitive and sustainable.**

**7. <u>Development of Pharmaceuticals Industry</u>**

**The Committee note that 'Scheme for Development of Pharma industry' is an Umbrella Scheme comprising of five sub-schemes (i)Assistance to Bulk Drug Industry for Common Facilitation Centres, (ii) Assistance to Medical Device Industry for Common Facilitation**

**Centres, (iii) Assistance to Pharmaceutical Industry (CDP-PS) (iv) Pharmaceuticals Technology Up-gradation Assistance Scheme (PTUAS) and (v) Pharmaceutical Promotion and Development Scheme (PPDS). During 2017-18 Rs 17.02 crores were allocated at BE stage which reduced to Rs 12.03 crores at RE stage and actual expenditure was just Rs. 0.77 crores. Now for the current year 2018-19 Rs 12.97 crores have been allocated. The committee note that department has not utilized the allocation made under three ongoing sub-schemes mentioned above at (iii), (iv) and (v) . Two sub-scheme mentioned above at (i) and (ii) are a fresh initiative of the Department and was considered by the SFC in its meeting held on 7/2/2018 only.**

**The Committee also note that the Department Action Plan for 2018-19 under 'Scheme for Development of Pharma industry' with budget allocation of Rs 12.97 crores are- (i) Initiation of Common Facility Centres in 2 Bulk Drug Parks under sub scheme Assistance to Bulk Drug Parks for Common Facility Centre which needs up to Rs.100 Crores, (ii) Initiation of Common Facility Centres in 2 Medical Device Parks under sub-scheme Assistance to Medical Device Parks for Common Facility Centre which needs up to Rs.25 Crores, (iii) Up-gradation to WHO-GMP standards of up to 100 units in private sector under sub-scheme Pharmaceuticals Technology Up-gradation Assistance Scheme(PTUAS), (iv) Initiation of Common Facilities Centres in 3 Clusters promoted by Special Purpose Vehicle (SPV) under sub-scheme Cluster Development Programme for Pharma Sector (CDP-PS) and (v) Conducting India Pharma and Indian Medical Expo; seminars, exhibitions etc. under Pharmaceutical Promotion & Development Scheme (PPDS).The Committee further note that the**

**Cluster Development Programme for Pharma Sector (CDP-PS) scheme could not take off despite the best efforts of the Government and Projects and Development India Limited (PDIL), the Project Management Consultant (PMC) had called for four expression of Interest (EOIs) and the responses were not encouraging in spite of the modification in the scheme and only one Special Purpose Vehicle (SPV) has been found suitable.**

**The Committee seriously note the gross underutilization of funds during 2017-18 which has impacted the implementation process of these sub-schemes. The Committee further note that the Department has clubbed these schemes under an umbrella programme which gives flexibility to utilize funds in these sub-schemes as and when needed. The Committee are of considered view that unless and until the problem of underutilization is duly addressed, no effective outcomes intended by these sub-schemes will be achieved. Thus the Committee recommend the Department to take necessary steps to ensure optimum utilization of allocated funds under this Scheme for Development of Pharmaceuticals industry and enhance the allocation at RE stage as the current allocation of Rs12.97 crores at BE stage is grossly insufficient for accomplishing the aforesaid Action Plan of the Department for the year 2018-19. The Committee further recommend the Department to take innovative steps to generate pharmaceutical industry attraction towards Cluster development programme so as to disseminate benefit of economies of scale and increase production of affordable medicines in the country at large scale.**

**8. Jan Aushadhi Scheme (PMBJP)**

**The Committee note that Pradhan Mantri Bhartiya Janaushadhi Pariyojana (PMBJP) was launched by the Department of Pharmaceuticals, Ministry of Chemicals & Fertilizers, Government of India in November, 2008 across the country. These specific outlets are now called "Pradhan Bhartiya Janaushadhi Pariyojana (PMBJP) Kendra's". The scheme is being implemented through an agency namely Bureau of Pharma PSUs of India (BPPI) (the implementing agency of PMBJP) which is working under the administrative control of Department of Pharmaceuticals, Ministry of Chemicals &Fertilizers, Government of India. During the year 2017-18, Rs. 74.62 crores have been allocated at RE stage and Rs.47.64 crores was released to BPPI but only Rs 29.63 crores have been the actual utilization under this scheme. During the current year 2018-19, the allocation at BE stage has been increased to Rs.84 crores. Further as per the three year plan of the PMBJP, 1000 more PMBJP Kendra's have been targeted to open in the country in each financial year beyond 2017-18 that is 2018-19 and 2019-2020.**

**The Committee appreciate that the Department has expanded the outreach of PMBJP kendras and as on 27.02.2018, 3,195 PMBJP Kendras' are functional in 33 States / Union Territories of the country. Further for smooth supply of medicines, surgical and consumables to PMBJP Kendras through Central Ware House (CWH) of Bureau of Pharma PSUs of India (BPPI) (the implementing agency of PMBJP), 8 Carrying & Forwarding (C&F) Agents and 53 Distributors have been appointed in different parts of the country. The product basket of the**

**scheme has also been expanded to cover more than 700 medicines and 154 surgicals & consumables covering all major therapeutic groups such as Anti-infective, Anti-diabetics, Cardio vasculars, Anti-cancers, Gastro-intestinal medicines, etc. However, the Committee observe that the current supply chain mechanism for 3195 functional Kendra is not sufficient to provide timely supply of generic drugs and medical devices to common people. Thus, the Committee recommend the Department to explore the feasibility for opening of Regional Warehouses and expand its Carrying & Forwarding (C&F) Agents and Distributors network on need basis in areas facing supply side limitations. They also recommend that a technology based real time tracking system from CWC to PMBJP Kendra be evolved to ensure pilferage free supply of generic medicines and medical devices.**

**9. <u>Revival/Restructuring of Public Sector Undertakings</u>**

**The Committee note that of the five PSUs, three viz. Indian Drug & Pharmaceuticals Limited (IDPL), Hindustan Antibiotic Limited (HAL) & Bengal Chemicals & Pharmaceuticals Limited (BCPL) are sick and referred to Board for Industrial & Financial Reconstruction (BIFR). Rajasthan Drugs & Pharmaceuticals Limited (RDPL) has reported losses since 2013-14 and is incipient sick. Karnataka Antibiotic & Pharmaceuticals Limited (KAPL) is the only profit making CPSE. The Committee also note that from 2015-16the Department has changed its scheme from Project Based Support to PSU to new scheme Assistance to PSUs. Under Assistance to PSUs Scheme during 2015-16 Rs.0.04 crores were allocated at BE stage which was withdrawn at RE stage. During 2016-17 Rs.0.10 crores were allocated at**

**BE and RE stage, however actual utilization was nil. During 2017-18 Rs.0.06 crores were allocated at BE and RE stage with nil actual utilization. For the current year 2018-19 again Rs.0.06 crores have been allocated.**

**Further the Committee note that the Cabinet meeting held on 28.12.2016 decided that only that much of surplus land of HAL, IDPL, RDPL and BCPL as would be required to meet the liabilities be sold through open competitive bidding to Government agencies and the outstanding liabilities be cleared from the sale proceeds. Voluntary Separation Scheme/ Voluntary Retirement Scheme also be implemented in these PSUs to pave way for their closure. Remaining part of the land should be managed in accordance with guidelines of Department of Investment and Public Asset Management (DIPAM) and Department of Public Enterprises (DPE) in this regard and if need be, vested in a SPV created for this purpose. After liabilities have been met, balance sheet cleansed and the Voluntary Separation Scheme/Voluntary Retirement Scheme effected, the Department to close IDPL and RDPL and HAL and BCPL be put up for strategic sale. The Committee also note that Cabinet Committee on Economic Affairs (CCEA) in its meeting held on 1.11.2017 has 'in principle' approved strategic disinvestment of 100% Government of India equity in Karnataka Antibiotics & Pharmaceuticals Limited (KAPL), Bengaluru through a two-stage auction process.**

**The Committee note that the allocation under Assistance to PSUs is only a token allocation, the reason is well known that is to keep the head open and alive for seeking more funds in future. However at the same time the Committee impress upon the Department to implement**

**the decisions of the Cabinet Committee on Economic Affairs (CCEA) dated 28.12.2016 and 1.11.2017 respectively. The Committee further recommend the Department to ensure accurate evaluation of PSUs assets before going for strategic sale to private players. The Committee also recommend the Department to focus on internal administrative streamlining and management reforms in RDPL in the same way as BCPL has done in 2017-18, till a final way out is reached.**

**New Delhi;**

**12 March, 2018**
**21 Phalguna, 1939 (Saka)**

**Anandrao Adsul**
**Chairperson**
**Standing Committee on**
**Chemicals and Fertilizers**

***MINISTRY OF CHEMICALS AND FERTILISERS***

DEMAND NO. 8

**Department of Pharmaceuticals**

*(In ₹ crores)*

| | Actual 2016-2017 | | | Budget 2017-2018 | | | Revised 2017-2018 | | | Budget 2018-2019 | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | Revenue | Capital | Total | Revenue | Capital | Total | Revenue | Capital | Total | Revenue | Capital | Total |
| Gross | 207.57 | 100.00 | 307.57 | 247.68 | 0.06 | 247.74 | 266.03 | 0.06 | 266.09 | 261.47 | 0.06 | 261.53 |
| *Recoveries* | ... | ... | ... | ... | ... | ... | ... | ... | ... | ... | ... | ... |
| *Receipts* | ... | ... | ... | ... | ... | ... | ... | ... | ... | ... | ... | ... |
| **Net** | **207.57** | **100.00** | **307.57** | **247.68** | **0.06** | **247.74** | **266.03** | **0.06** | **266.09** | **261.47** | **0.06** | **261.53** |
| A. The Budget allocations, net of recoveries, are given below: | | | | | | | | | | | | |
| **CENTRE'S EXPENDITURE** | | | | | | | | | | | | |
| **Establishment Expenditure of the Centre** | | | | | | | | | | | | |
| 1. Secretariat | 12.03 | ... | 12.03 | 13.30 | ... | 13.30 | 13.30 | ... | 13.30 | 14.00 | ... | 14.00 |
| 2. National Pharmaceutical Pricing Authority | 10.68 | ... | 10.68 | 15.00 | ... | 15.00 | 14.42 | ... | 14.42 | 11.50 | ... | 11.50 |
| **Total-Establishment Expenditure of the Centre** | **22.71** | **...** | **22.71** | **28.30** | **...** | **28.30** | **27.72** | **...** | **27.72** | **25.50** | **...** | **25.50** |
| **Central Sector Schemes/Projects** | | | | | | | | | | | | |
| 3. National Institutes of Pharmaceutical Education and Research (NIPERs) | 127.48 | ... | 127.48 | 127.73 | ... | 127.73 | 151.66 | ... | 151.66 | 135.00 | ... | 135.00 |
| 4. Jan Aushadhi Scheme | 49.75 | ... | 49.75 | 74.62 | ... | 74.62 | 74.62 | ... | 74.62 | 84.00 | ... | 84.00 |
| 5. Development of Pharmaceutical Industry | 7.63 | ... | 7.63 | 17.03 | ... | 17.03 | 12.03 | ... | 12.03 | 12.97 | ... | 12.97 |
| 6. Consumer Awareness Publicity and Price Monitoring | ... | ... | ... | ... | ... | ... | ... | ... | ... | 4.00 | ... | 4.00 |
| **Total-Central Sector Schemes/Projects** | **184.86** | **...** | **184.86** | **219.38** | **...** | **219.38** | **238.31** | **...** | **238.31** | **235.97** | **...** | **235.97** |
| **Other Central Sector Expenditure** | | | | | | | | | | | | |
| **Public Sector Undertakings** | | | | | | | | | | | | |
| 7. Assistance to PSUs | ... | 100.00 | 100.00 | ... | 0.06 | 0.06 | ... | 0.06 | 0.06 | ... | 0.06 | 0.06 |
| ***Grand Total*** | ***207.57*** | ***100.00*** | ***307.57*** | ***247.68*** | ***0.06*** | ***247.74*** | ***266.03*** | ***0.06*** | ***266.09*** | ***261.47*** | ***0.06*** | ***261.53*** |
| **B. Developmental Heads** | | | | | | | | | | | | |
| **Economic Services** | | | | | | | | | | | | |
| 1. Industries | 195.54 | ... | 195.54 | 202.86 | ... | 202.86 | 213.86 | ... | 213.86 | 213.95 | ... | 213.95 |
| 2. Secretariat-Economic Services | 12.03 | ... | 12.03 | 13.30 | ... | 13.30 | 13.30 | ... | 13.30 | 14.00 | ... | 14.00 |

*No. 8/Department of Pharmaceuticals*

*(In ₹ crores)*

| | Actual 2016-2017 | | | Budget 2017-2018 | | | Revised 2017-2018 | | | Budget 2018-2019 | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | Revenue | Capital | Total | Revenue | Capital | Total | Revenue | Capital | Total | Revenue | Capital | Total |
| 3. Loans for Chemical and Pharmaceutical Industries | ... | 100.00 | 100.00 | ... | 0.06 | 0.06 | ... | 0.06 | 0.06 | ... | 0.06 | 0.06 |
| **Total-Economic Services** | **207.57** | **100.00** | **307.57** | **216.16** | **0.06** | **216.22** | **227.16** | **0.06** | **227.22** | **227.95** | **0.06** | **228.01** |
| **Others** | | | | | | | | | | | | |
| 4. North Eastern Areas | ... | ... | ... | 31.52 | ... | 31.52 | 38.87 | ... | 38.87 | 33.52 | ... | 33.52 |
| **Total-Others** | **...** | **...** | **...** | **31.52** | **...** | **31.52** | **38.87** | **...** | **38.87** | **33.52** | **...** | **33.52** |
| **Grand Total** | **207.57** | **100.00** | **307.57** | **247.68** | **0.06** | **247.74** | **266.03** | **0.06** | **266.09** | **261.47** | **0.06** | **261.53** |

1. **Secretariat:** The provision is for the Salary and Establishment Expenditure of Department of Pharmaceuticals.

2. **National Pharmaceutical Pricing Authority:** The provision is for the Secretariat and Establishment Expenditure of NPPA,

3. **National Institutes of Pharmaceutical Education and Research (NIPERs):** The provision is for the 7 NIPERs which are operational and also for the 4 NIPERs which are are proposed.

4. **Jan Aushadhi Scheme:** Under the Jan Aushadhi Scheme for effective implementation of Pradhan Mantri Bhartiya Janaushadhi Pariyojana(PMBJP).

5. **Development of Pharmaceutical Industry:** The scheme for Development of Pharmaceuticals Industry consists of a number of sub scheme such as: Pharmaceuticals Promotion Development Scheme (PPDS) , Cluster Development , assistance to Bulk Drug Industry for Common Facilitation Centre and assistance to Medical Device for Common Facilitation Centre etc.

6. **Consumer Awareness Publicity and Price Monitoring:** The provision is for Consumer Awarness, Publicity and providing support to State resource units.

7. **Assistance to PSUs:** These are provisions under loan kept for the 6 Pharmaceuticals Public Sector Undertakings.

**ANNEXURE-II**

**RECOMMENDATIONS OF NITI AAYOG ON NIPERs**

**1.** The NIPERs need to re-engineer their business model to become the "IITs of the Pharmaceuticals sector". The model may be based on an objective assessment of outcomes to ensure highest standards of pharmaceuticals education and research in the country.

**2.** Need for more NIPERs? : Given the pace of development of the existing NIPERs (except Mohali), there is a need to consolidate the existing ones, at this juncture, rather than setting up new NIPERs.

Strengthening: 5 NIPERs (Mohali, Ahmedabad, Guwahati, Hyderabad and Raebareli) which have been allotted land and are in various stages of functioning may be continued. These institutes need to be provided with adequate resources (especially for setting up laboratories) in order to help improve their performance.

Continuation or not: 2 NIPERs (Hajipur and Kolkata) witch have not been allotted land even after 10 years, may be re-considered for continuation. In case, these are decided to be closed, resources and students in these two NIPERs may be redistributed among the remaining institutes. It is also recommended that instead of opening new NIPERs, the limited budgetary resources be used for upgrading the existing institutes. The new announced NIPERs may be co-located, suggestively with Council for Scientific and Industrial Research (CSIR) laboratories, located near pharma hubs to save on capital costs.

[16]NIRF 2017 report of NIPER-Mohali and NIPER-Hyderabad; Annual Work Plan and Budget report of NIPER-Mohali for the year 2016-17
[17]NIPER-Mohali: Rs. 31.57 Crore; Rs. 26.05 Crore; JamiaHamdard: Rs. 5.71 Crore (Opex 2015-16; Source: NIRF 2017)

**3.** Courses: As per an industry estimate, the projected human resource requirement in the pharmaceuticals sector by 2020 is around 26 lakh. In order to meet the existing and growing demand of the pharmaceutical sector, under-graduate Courses should be immediately started in all the NIPERs. With the addition of UG courses, PhD students will also be involved in teaching, which will be a value addition.

- Similarly, PG/PhD seats need to be increased drastically, at least to match up to the level of best pharma private college/institute in the country. Integrated

PG and PhD courses, executive education courses like short-term certificate courses/ training programmes/ refresher courses/ online/distance education diploma and one year executive courses in pharmaceuticals may be initiated.

- Courses require revision to reflect the national requirements to fulfill 'Make in India'. Pharmaceutical analysis, Pharmaceutics, Regulatory affairs/Quality Certification/Quality Assurance and Pharmatech/engineering, Biopharmaceuticals/chemistry/biology exposure are the five most important subjects which must be taught at every NIPER.

- The faculty and technical staff at NIPERs should take steps such as conducting mobile camps in pharma industrial places, to enhance knowledge/ skills of SME and MSME especially in the field of Quality control /quality assurance/regulatory affairs/Pharmatech/engineering/Bioequivalence.

**4.** Faculty: All posts of Director need to be filled up expeditiously. In addition, qualifications for all the posts (including Directors) need to be made stringent upon adequate experience in pharmaceutical research. The faculty posts need to be filled up with a mix of full time/ part-time and guest faculty.

A periodic performance evaluation of each faculty (full time as well as part time) should also be done on outcome based criteria. This may be linked to their career promotions. While the criteria may be finalised by the Apex council (described later), the criteria could include number of patents filed, publications in peer reviewed journals, students placed, funding18 brought-in, consultancies done, etc.

**5.** NIPERs need to establish strong linkages with:

- Academic institutes like IITs to develop technology which can be used by the institute for innovations;

[18]As per the NIPER Statues 2003, the innovator- principal contributors and support staff get 95% of the cost of contract research projects and consultancy which is a good enough share to motivate faculty to undertake more contract research projects and provide consultancy. Hence, this should be an important evaluation parameter for the faculty

- Post graduate medical institutes such as PGIMER, AIIMS, etc. for moving towards clinical research;
- Industry to promote labs (such as Central Instrumentation Lab, Technology Development Centre and Toxicological Centre) which can be utilised by the industry through a user free mechanism.
- Other labs, industrial hubs[19] and prominent research labs such as CSIR labs[20,] etc. to participate in drug discovery & development, students training and faculty sharing.

**6.** Capacity Building: In order to enhance the quality of students passing out and help them place better in the industry, emphasis needs to be given to research which can be used by the industry. Some suggested steps include:

- Incentivising faculty, both financially and otherwise, for patents;

- Student exchange programmes through university tie-ups need to be increased and MoUs may be finalized with international universities;

- Incorporating/strengthening tie curriculum of the institutes as per the industry needs. These include study related to Manufacturing process, Pharmaceutical analysis and Quality control subjects.

- PhD Students should also take up the task of teaching PG& UG[21] students within NIPERs.
- The concept of 'pharma-perceptors' can be brought in where the institute appoints pioneers/ expert in the industry to interact and teach the students the requirements of the industry.

**7.** Financing: The budgetary support by the government would need to continue, at least in the immediate future, for these institutes. The quantum sought needs to be re-visited and may need to be prioritized for addressing their critical requirements such as labs and operating costs[22] as explained in previous paragraphs. Further, steps to reduce the financial grants and generate funds from alternate source are:

a. Increase in revenue generation through drug discovery & development chain, especially industry engagement, to promote step-2[23] (i.e. pre-clinical research).

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19 Hyderabad is called the bulk drug capital of India, with nearly one third of India's total bulk drug production (Source: Bioasia 2015); Hyderabad and Vishakhapatnam house the largest biotech cluster and bulk drum market.

20 NIPER- Hyderabad, Kolkata and Raebareli have CSIR-IICT, CSIR-IICB and CSIR-CDRI labs as their mentor institutes

21 Upon commencement

[22]Pg 7, Financial requirement appraisal

[23] Please refer Diagram-1

b. Consultancy: A minimum number of consultancies by each member of faculty may be prescribed which will not only generate revenue, but also enhance the adoption of cutting-edge technologies.

c. Stipend: The stipend given to students should be funded through various government and private fellowships/projects like those of CSIR, DBT, etc. and students must be encouraged to complete/apply for these fellowships as a source of stipend rather that depending solely on the institute.

d. Lease: Land may be leased out to industry to set up R&D units/ Good Lab Practices (GLP) labs which can also be utilised by students/faculty. Space may also be leased out for commercial activities such as essential utility shops, restaurants, etc.

e. Vertical Structure: The resources may be utilized for vertical expansion of the five institutes. Due to scarcity of land and financial constraints, vertical expansion (as per the FAR) of the institute should be referred rather than a horizontal spread leaving a green belt within the campus which may be used to have herbal gardens, etc. This will aid in inputs for research and can be an additional financial source as well.

**8.** Facilities for Drug Discovery: The value chain for drug discovery with a focus on research on Active Pharmaceutical Ingredients, Pre-clinical Trials[24] etc. needs to be established in all the five NIPERs. The central instrumentation labs can be an important source of revenue generation within the institute with appropriate industry linkages. All NIPERs should be centres of excellence[25] for drug discovery and development eg. Pharmacovigilance, pharmacodynamics, regulatory affairs, pharmaceutical analysis, biopharmaceuticals, etc. This would, to a certain extent, reduce over dependence on importing APIs over a period of time.

Similarly, World Health Organization-Good Laboratory Practices certifies labs will also attract industry towards institutes and these institutes need to work toward having more GLP facilities.

**9.** Governance

Apex Council: An overcharging Council (Apex Council) may be constituted to ensure co-ordination across all the NIPERs. The Council may have complete autonomy in the functioning of the NIPERs such for prescribing curriculum, fee &stipend, establish industry and academia linkages within the country, faculty evaluation and the outcome, etc. of all the NIPETs. The Government should only have powers for policy directions and sanctioning of regular posts. The Council may comprise the Directors of the NIPERs and Directors, IIT, IISs and DG, ICMR, leads from pharma/biopharma.

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[24]with linkages as mentioned in para 3.1.7

[25]NIPER-Mohali: QC/QA/Regulatory affairs: NIPER-Hyderabad: API Chemistry and Biopharmaceuticals/ Biology; NIPER-Ahmedabad: Pharmaceutics

f. Till such time an Apex Council in constituted, a Committee comprising Directors of all the institutes may be constituted to ensure immediate addition/ updation/ revision of courses/curriculum across the Institutes and filling up of the vacant post. The Committee may also recommend fee structure stipend, use fee to be charged from industry, advise on evaluation criteria of students, stiff and the institute. The institutes should have complete autonomy in their functioning except for policy directions and sanctioning of posts, which should be with the government.

**10.** Evaluation of NIPERs: There should be an outcome based assessment, using well-defined acceptable criteria and evaluation of NIPERs (may be conducted under the aegis of Apex Council). To decide the evaluation criteria for ranking NIPERs, some of the existing national and international ranking systems, FIP Pharma education quality framework can be used as an input for evaluation. This may be linked with release of certain percentage of funds from the Government.

**ANNEXURE - III**

## MINUTES OF THE SIXTH SITTING OF THE STANDING COMMITTEE ON CHEMICALS & FERTILIZERS

## (2017-18)

The Committee sat on Wednesday, the 21st February, 2018 from 1430 hrs. to 1630 hrs. in Committee Room 'C', Parliament House Annexe, New Delhi.

**PRESENT**

**Shri Anandrao Adsul - Chairperson**

**MEMBERS**

**LOK SABHA**

2. Shri George Baker
3. Shri Sankar Prasad Datta
4. Dr. (Smt.) Ratna De (Nag)
5. Shri Innocent
6. Dr. (Prof.) Azmeera Setaram Naik
7. Shri K. Ashok Kumar
8. Shri Chhedi Paswan
9. Shri S. Rajendran
10. Dr. Kulamani Samal
11. Dr. Krishna Pratap Singh

**RAJYA SABHA**

12. Shri Biswajit Daimary

13. Shri Prem Chand Gupta

14. Shri B. K. Hariprasad

15. Dr. Bhushan Lal Jangde

**SECRETARIAT**

1. Shri Vinod Kumar Tripathi - Joint Secretary

2. Shri A. K. Srivastava - Director

3. Shri U. C. Bharadwaj - Deputy Secretary

**LIST OF WITNESSES**

***I. MINISTRY OF CHEMICALS AND FERTILIZERS***

***(DEPARTMENT OF PHARMACEUTICALS)***

| | | |
|---|---|---|
| 1. | Shri Jai Priye Prakash | Secretary |
| 2. | Ms. Meenakshi Gupta | Additional Secretary & Financial Advisor |
| 3. | Shri Rajneesh Tingal | Joint Secretary |
| 4. | Smt. Bandhula Sagar | CCA |

***II. REPRESENTATIVES OF NPPA***

| | | |
|---|---|---|
| 1. | Shri Bhupendra Singh | Chairman, National Pharmaceuticals Pricing Authority (NPPA) |

***III. REPRESENTATIVES OF PSUs***

| | | |
|---|---|---|
| 1. | Ms. Nirja Saraf | MD, Hindustan Antibiotics Limited (HAL) |
| 2. | Shri Biplab Chatterjee | CEOBureau of Pharma Public Sector Undertakings of India (BPPI) |

2. At the outset, Hon'ble Chairperson welcomed the Members of the Committee and representatives of the Ministry of Chemicals & Fertilizers (Department of Pharmaceuticals) and other officials to the sitting. Their attention was invited to the provisions contained in Direction 55(1) of the Directions by the Speaker regarding confidentiality of the Committee's proceedings.

3. After the witnesses introduced themselves, a representative of the Department of Pharmaceuticals made power point presentation to the Committee regarding Demands for Grants 2018-19 of the Department of Pharmaceuticals.

4. During the discussion, the Hon'ble Chairperson and Members of the Committee raised queries on several issues such as:-

(i) Underutilization of funds allocated to the Department;

(ii) Shortage of funds allocated for various schemes of the Department;

(iii) Implementation of 'Pradhan Mantri Bhartiya Janaushadhi Pariyojana' and lack of awareness among general public with regard to Jan Aushadhi Kendras;

(iv) Revival of BCPL and replication of same model in other sick PSUs-HAL, IDPL and RDPL;

(v) Functioning of NIPER and implementation of NITI Aayog recommendation on NIPERs;

(vi) Role of NPPA in putting some ceiling on prices of medicines outside National essential Medicine List and also efforts made in coordination with Central Drug Controller in controlling sale of spurious and expired medicines in backward states; and

(viii) Implementation of Cluster Development Programme for Pharma Sector (CDP-PS) and token allocation under assistance to PSU scheme.

5. The Secretary, Department of Pharmaceuticals and other officials responded to the aforesaid concerns/issues raised by the Committee.

6. The Chairperson thanked the witnesses for appearing before the Committee as well as for furnishing valuable information to the Committee. They were also asked to provide required information not readily available at the earliest.

7 A copy of the verbatim record of the proceedings of the sitting has been kept.

*The Committee then adjourned.*

**MINUTES OF THE NINTH SITTING OF THE STANDING COMMITTEE ON CHEMICALS & FERTILIZERS**

**(2017-18)**

The Committee sat on Monday, the 12 March, 2018 from 1500 hrs. to 1530 hrs. in Room No. 139, Parliament House Annexe, New Delhi.

**PRESENT**

**Shri Anandrao Adsul - Chairperson**

**MEMBERS**

**LOK SABHA**

2. Shri George Baker
3. Smt. Anju Bala
4. Smt. Veena Devi
5. Shri K. Ashok Kumar
6. Shri Chhedi Paswan
7. Shri S. Rajendran
8. Dr. Kulamani Samal
9. Dr. (Smt.) Ratna De (Nag)

**RAJYA SABHA**

10. Dr. Bhusan Lal Jangde
11. Shri Ranvijay Singh Judev
12. Shri B. K. Hariprasad

**SECRETARIAT**

1. Shri Vinod Kumar Tripathi - Joint Secretary
2. Shri A. K. Srivastava - Director
3. Shri U. C. Bharadawaj - Deputy Secretary

2. At the outset, the Hon'ble Chairperson welcomed the Members of the Committee.

3. The Committee thereafter took up for consideration and adoption the following draft Reports:

(i) xxx xxx xxx
(ii) xxx xxx xxx

(iii) Draft report on 'Demands for Grants 2018-19' (Department of Pharmaceuticals.

4. After deliberations the Draft Reports were adopted by the Committee. without any changes/amendments.

5. The Committee authorised the Chairperson to make consequential changes, if any, arising out of the factual verification of the Reports by the Department of Fertilizers, Department of Chemicals and Petrochemicals and Department of Pharmaceuticals and present the same to both the Houses of Parliament.

***The Committee then adjourned.***